UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 20-F

☐ REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934
OR

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2012

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

☐ SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of event requiring this shell company report_____
For the transition period from_____ to _____

Commission file number: 000-28508

Flamel Technologies S.A.

_____
(Exact name of Registrant as specified in its charter)

Not Applicable

_____
(Translation of Registrant's name into English)

Republic of France

_____
(Jurisdiction of incorporation or organization)

Parc Club du Moulin à Vent
33, avenue du Docteur Georges Levy
69693 Vénissieux Cedex France

_____
(Address of principal executive offices)

Siân Crouzet
Principal Financial Officer
Parc Club du Moulin à Vent
33, avenue du Docteur Georges Levy
69693 Vénissieux Cedex France
Fax: +33 472 78 34 35
Tel: +33 472 78 34 34

_____
(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

Securities registered or to be registered pursuant to Section 12(b) of the Act.

Title of each class	Name of Exchange on which Registered
Ordinary Shares, nominal value 0.122 Euros per share, represented by American Depositary Shares (as evidenced by American Depositary Receipts), each representing one Ordinary Share	**NASDAQ Global Market**

Securities registered or to be registered pursuant to Section 12(g) of the Act. None.

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act. None.

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report.

24,962,250 Ordinary Shares, nominal value 0.122 Euros per Ordinary Share

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes ☐ No ☒

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.

Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of “accelerated filer and large accelerated filer” in Rule 12b-2 of the Exchange Act.:

Large accelerated filer ☐ Accelerated filer ☒ Non-accelerated filer ☐

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP ☒
International Financial Reporting Standards as issued by the International Accounting Standards Board ☐
Other ☐

If “Other” has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow.

Item 17 ☐ Item 18 ☐

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes ☐ No☒

TABLE OF CONTENTS

As used herein, references to the Company, 'we,' 'us,' 'our,' the Registrant and Flamel refer to Flamel Technologies S.A. and its consolidated subsidiary, Flamel Technologies, Inc., unless the context indicates otherwise. References to Shares herein refer to (i) the Ordinary Shares of Flamel, nominal value 0.122 Euros per Ordinary Share (the 'Ordinary Shares') and (ii) Flamel's American Depositary Shares, each of which represents one Ordinary Share ('ADSs'). The ADSs are evidenced by American Depositary Receipts ('ADRs'). Ordinary Shares and ADSs are referred to herein as 'Shares.'

The following product or technology designations are trademarks of the Company: Basulin®, Flamel Technologies®, Micropump®, Medusa®, Trigger Lock™, Delivax®, LiquiTime®, Hycet®, Vazculep™, Bloxiverz™ and Neoversa™.

Flamel publishes its financial statements in U.S. dollars. In this annual report, references to 'dollars' or '$' are to U.S. dollars and references to 'Euros' or 'EUR' or '€' are to the currency of the European Union as used in the Republic of France. Except as otherwise stated herein, all monetary amounts in this annual report have been presented in dollars. Solely for the convenience of the reader, this annual report contains translations of certain Euro amounts into dollars at specified rates. See 'Item 3. Key Information - Exchange Rates' for information regarding the rates of exchange between the Euro and the dollar in each of the previous five years.

SPECIAL NOTE REGARDING FORWARD-LOOKING INFORMATION

This annual report contains forward-looking statements. We may make additional written or oral forward-looking statements from time to time in filings with the Securities and Exchange Commission or otherwise. The words "will," "may," "believe," "expect," "anticipate," "estimate," "project" and similar expressions identify forward-looking statements, which speak only as of the date the statement is made. Such forward-looking statements are within the meaning of that term in Section 27A of the Securities Act of 1933 as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Although we believe that our expectations are based on reasonable assumptions within the bounds of our knowledge of our business and operations, our business is subject to significant risks and there can be no assurance that actual results of our development and manufacturing activities and our results of operations will not differ materially from our expectations. Factors that could cause actual results to differ from expectations include, among others, those specified in "Risk Factors" beginning on page 3, some of which are highlighted below:

- we depend on a few customers for the majority of our revenues, and the loss of any one of these customers could reduce our revenues significantly.

- although products that incorporate our drug delivery technologies and development products acquired through our acquisition of Éclat Pharmaceuticals, LLC, or Éclat, may appear promising at their early stages of development and in clinical trials, none of these potential technologies or products may reach the commercial market for any number of reasons.

- our focusing on (i) the development and licensing of five versatile, proprietary drug delivery platforms, (ii) the development of novel, high-value products based on our drug delivery platforms and (iii) as a result of our acquisition of Éclat, the development, approval, and commercialization of niche branded and generic pharmaceutical products in the U.S., rather than primarily on collaborative agreements with pharmaceutical and biotechnology companies, may not be successful.

- revenues from our drug delivery business depend primarily on pharmaceutical and biotechnology companies successfully developing products that incorporate our drug delivery platforms.

- we must invest substantial sums in research and development in order to remain competitive, and we may not fully recover these investments.

- we must comply with various covenants and obligations under the note agreement with Éclat Holdings, related to the acquisition of Eclat and our failure to do so could adversely affect our ability to operate our business, develop our product portfolio or pursue certain opportunities.

- we depend upon a single site to manufacture our drug delivery products, and any interruption of operations could have a material adverse effect on our business..

- we depend upon a limited number of suppliers for certain raw materials used in our products, and any failure to deliver sufficient quantities of supplies could interrupt our production process and could have a material adverse effect on our business.

- if our competitors develop and market technologies or products that are more effective or safer than ours, or obtain regulatory approval and market such technologies or products before we do, our commercial opportunity will be diminished or eliminated.

- if we cannot keep pace with the rapid technological change in our industry, we may lose business, and our drug delivery platforms and drug products could become obsolete or noncompetitive.

- if we cannot adequately protect our technology and proprietary information, we may be unable to sustain a competitive advantage.

- even if we and our partners obtain necessary regulatory approvals, our products and platforms may not gain market acceptance.

- our collaborative arrangements may give rise to disputes over commercial terms, contract interpretation and ownership of intellectual property and may adversely affect the commercial success of our products.

- third parties have claimed, and may claim in the future, that our platforms, or the products in which they are used, or our products infringe on their rights and we may incur significant costs resolving these claims or may not be able to resolve.

- we can offer no assurance that any patents issued to us will provide us with competitive advantages or will not be infringed, challenged, invalidated or circumvented by others, or that the patents or proprietary rights of others will not have an adverse effect on our ability to do business.

- if our third party collaborative partners face generic competition for their products, our revenues and royalties from such products may be adversely affected.

- healthcare reform and restrictions on reimbursements may limit our financial returns.

- fluctuations in foreign currency exchange rates and the impact of the European sovereign debt crisis may clause fluctuations in our financial results.

- products that incorporate our drug delivery platforms and Éclat development products in are subject to regulatory approval. If such approvals are not obtained, or are delayed, our revenues may be adversely affected.

- we are subject to U.S.federal and state laws prohibiting “kickbacks” and false claims that, if violated, could subject us to substantial penalties, and any challenges to or investigation into our practices under these laws could cause adverse publicity and be costly to respond to, causing harm to our business.

- companies to which we have licensed our technologies are subject to extensive regulation by the FDA and other regulatory authorities. Their failure to meet these regulatory requirements could adversely affect our business.

- we may face product liability claims related to participation in clinical trials or the use or misuse of our products or third party products that incorporate our technologies.

- if we use biological and hazardous materials in a manner that causes injury, we may be liable for significant damages.

- we may fail to realize the anticipated benefits expected from the acquisition of Éclat and its portfolio of pipeline products.

- if we choose to acquire new and complementary businesses, products or technologies, we may be unable to complete these acquisitions or to successfully integrate them in a cost effective and non-disruptive manner.

- our share price has been volatile and may continue to be so.

- because we have had limited commercial sales, investors in our shares may have difficulty evaluating our prospects.

- if we are not profitable in the future, the value of our shares may fall.

- our operating results may fluctuate, which may adversely affect our share price.

- we currently do not intend to pay dividends, and cannot assure shareholders that we will make dividend payments in the future.

- our largest shareholders own a significant percentage of our share capital and hold the related voting rights of the Company.

Forward-looking statements are subject to inherent risks and uncertainties, some of which cannot be predicted or quantified. Future events and actual results could differ materially from those set forth in, contemplated by or underlying the forward-looking statements. We undertake no obligation to update these forward-looking statements as a result of new information, future events or otherwise. You should not place undue reliance on these forward-looking statements. Statements in this annual report including those set forth in ‘Risk Factors’ in this report, describe factors, among others, that could contribute to or cause such differences.

PART I

ITEM 1. Identity of Directors, Senior Management and Advisers

Not applicable.

ITEM 2. Offer Statistics and Expected Timetable

Not applicable.

ITEM 3. Key Information

Selected Financial Data

The selected consolidated financial data as of and for each of the five years ended December 31, 2012 are derived from the Consolidated Financial Statements of the Company, which have been prepared in accordance with U.S. GAAP and audited by an independent registered accounting firm with the Public Company Accounting Oversight Board (United States). The selected consolidated financial data of the Company set forth below are qualified by reference to, and should be read in conjunction with, 'Item 5. Operating and Financial Review and Prospects' and the Consolidated Financial Statements and the Notes related thereto appearing elsewhere in this annual report.

Statement of Operations Data*:

	2008	2009	2010	2011	2012
Revenues	38,619	42,118	37,094	32,600	26,101
Cost and Expenses	(51,801)	(53,871)	(46,934)	(42,183)	(34,464)
Income (Loss) from Operations	(13,182)	(11,753)	(9,840)	(9,583)	(8,363)
Interest and foreign exchange gain (loss), net	1,417	342	549	867	331
Other income	181	(28)	525	134	102
Income (loss) before income tax	(11,584)	(11,439)	(8,766)	(8,582)	(7,930)
Income tax benefit (expense)	(500)	-	(209)	(192)	4,702
Net income (loss)	(12,084)	(11,439)	(8,975)	(8,774)	(3,228)
Income (Loss) from Operations per ordinary share	$ (0.55)	$ (0.49)	$ (0.40)	$ (0.39)	$ (0.33)
Basic earnings (loss) per ordinary share.	$ (0.50)	$ (0.47)	$ (0.37)	$ (0.36)	$ (0.13)
Diluted earnings (loss) per ordinary share	$ (0.50)	$ (0.47)	$ (0.37)	$ (0.36)	$ (0.13)
Basic weighted average number of shares outstanding (in thousands).	24,082	24,225	24,411	24,669	25,135
Diluted weighted average number of shares outstanding (in thousands)	24,082	24,225	24,411	24,669	25,135
Dividends per share	-	-	-	-	-

* in thousands of U.S. dollars, except share and per share data

Balance Sheet Data*:

	2008	2009	2010	2011	2012
Cash, Cash equivalents & marketable securities	$ 37,078	$ 44,068	$ 31,344	$ 24,491	$ 9,155
Working capital**	38,934	44,185	25,941	18,338	10,726
Total assets	91,861	94,296	74,614	69,402	117,311
Long term liabilities (excluding deferred revenues)	22,859	20,744	15,641	19,763	72,267
Shareholders' equity	48,546	44,863	36,305	29,794	30,504

* in thousands of U.S. dollars

** working capital is calculated by subtracting current liabilities from current assets

Exchange Rates:

Flamel publishes its financial statements in dollars. The reporting currency of the Company and its wholly-owned subsidiary is the U.S. dollar as permitted by the SEC for a foreign private issuer (S-X Rule 3-20(a)). All assets and liabilities in the balance sheets of the Company, whose functional currency is the Euro, except those of the U.S. subsidiary whose functional currency is the U.S. dollar, are translated into U.S. dollar equivalents at exchange rates as follows: (1) asset and liability accounts at year-end rates, (2) income statement accounts at weighted average exchange rates for the year, and (3) shareholders' equity accounts at historical rates. Corresponding translation gains or losses are recorded in shareholders' equity.

However, currently a significant portion of the Company's expenses are denominated in Euros. For information regarding the effects of currency fluctuations on the Company's results, see 'Item 5. Operating and Financial Review and Prospects.'

The following table sets forth the high, low and average exchange rates for the Euro against the U.S. dollar in each of the last five years and in each of the previous six months.

Year Ended December 31, Euro to U.S. Dollar:	**High**	**Low**	**Average Rate[1]**
2012	1.3454	1.2089	1.2856
2011	1.4882	1.2889	1.3917
2010	1.4563	1.1942	1.3268
2009	1.512	1.2555	1.3933
2008	1.599	1.246	1.4706
2007	1.4874	1.2893	1.37064

Previous Six Months, Euro to U.S. Dollar:	**High**	**Low**	**Average Rate[1]**
March 2013	1.3090	1.2768	1.2964
February 2013	1.3644	1.3077	1.3359
January 2013	1.3550	1.3012	1.3288
December 2012	1.3302	1.2905	1.3119
November 2012	1.2994	1.2694	1.2828
October 2012	1.3120	1.2877	1.2974

[1] Annual totals represent the average of the noon buying rates for Euros of each business day during the relevant period, according to the 'Banque de France'. Monthly totals represent the average of the noon buying rates for Euros for each business day during the relevant month according to the 'Banque de France'.

The exchange rate for the Euro against the U.S. dollar as of April 26, 2013, was $1.2999 to € 1.00. The Company makes no representation that Euro amounts have been, could have been or could be converted into dollars at any of the exchange rates referred to herein as of a given date.

Risk Factors

Our business faces many risks. The risks described below may not be the only risks we face. Additional risks that we do not yet know of or that we currently believe are immaterial may also impair our business operations. If any of the events or circumstances described in the following risks actually occur, our business, financial condition or results of operations could suffer, and the trading price of our securities could decline. As a result, you should consider all of the following risks, together with all of the other information in this Annual Report on Form 20-F, before making an investment decision regarding our securities.

Risks Relating to Our Business and Industry

We depend on a small number of customers for the majority of the revenues related to our drug delivery platforms, and the loss of any one of these customers could reduce our revenues significantly.

We depend on a small number of customers for the majority of our revenues from our drug delivery platforms. Revenue from GlaxoSmithKline plc (GSK) generated 61% of total revenues in 2012. The termination of our relationship with GSK and our failure to broaden our customer base could cause our revenues to decrease significantly and result in losses from our operations. Further, we may be unable to negotiate favorable business terms with customers and partners that represent a significant portion of our revenues. If so, our revenues and gross profits, if any, may not grow as expected or may not grow at a rate sufficient to make us profitable.

Our focusing on (i) the development and licensing of five versatile, proprietary drug delivery platforms, (ii) the development of novel, high-value products based on our drug delivery platforms and (iii) as a result of our acquisition of Éclat, the development, approval, and commercialization of niche branded and generic pharmaceutical products in the U.S., rather than primarily on collaborative agreements with pharmaceutical and biotechnology companies, may not be successful.

We have relied primarily over recent years on our collaborative agreements and relationships with pharmaceutical and biotechnology companies as partners with respect to our drug delivery platforms and our change in focus to the development of novel, high-value products based on our drug delivery platforms and (iii) as a result of our acquisition of Éclat, the development, approval, and commercialization of niche branded and generic pharmaceutical products in the US may not be successful in the near or long term and negatively impact our business, financial condition, and results of operations, and further increase our research and development expenses.

Our current revenues from our drug delivery business primarily depend on third party pharmaceutical and biotechnology companies successfully developing products that incorporate our drug delivery platforms.

We market and sell our technologies to third parties who incorporate our technologies into their products. We depend upon collaborative agreements with pharmaceutical and biotechnology companies to develop, test, obtain regulatory approval for and commercialize products that incorporate our drug delivery technologies. We currently have collaborative agreements or relationships with GSK, Theralpha SAS, Digna Biotech SL, Eagle Pharmaceuticals, Inc. and other pharmaceutical and biotechnology companies whose identities remain confidential.

The number of products that our partners successfully develop under these collaborative agreements will affect our revenues. We cannot control the timing or other aspects of the development or marketing by our partners of their products that incorporate our technologies and may not be informed by our partners concerning the timing and other aspects of their development or marketing efforts. The failure of one or more of our partners to develop successful products that incorporate our technologies or to perform as we expect under our agreements with them could have a material adverse effect on our business, financial condition and results of operations. We face risks relating to our collaborative agreements, including risks that:

- our collaborative agreements may not result in any new commercial products;
- the existing commercial products developed under our collaborative agreements may not be successful;
- our pharmaceutical and biotechnology company partners may not successfully obtain regulatory approval in a timely manner, or at all, and may not market any commercial products;
- we cannot control the amount and timing of resources that our pharmaceutical and biotechnology company partners devote to the development or commercialization of products using our technologies or to the marketing and distribution of those products;
- we may not be able to meet the milestones established in current or future collaborative agreements;
- we may not be able to successfully develop new drug delivery platforms that would be attractive to potential pharmaceutical or biotechnology company partners;
- our collaborative partners may terminate their relationships with us; and
- our collaborative partners may enter bankruptcy or otherwise dissolve.

Although products that incorporate our drug delivery platforms and products in development may appear promising at their early stages of development and in clinical trials, none of these potential platforms or products may reach the commercial market for a number of reasons.

Drug development is an inherently uncertain process with a high risk of failure at every stage of development. Successful research and development of pharmaceutical products is difficult, expensive and time consuming. Many product candidates fail to reach the market. We intend to continue to enhance our current technologies and pursue additional proprietary drug delivery platforms. Our success will depend on the discovery and the successful commercialization of products that can utilize our drug delivery platforms and development products from Éclat. If products incorporating our drug delivery platforms or our development products fail to reach the commercial market, our future revenues would be adversely affected.

Even if our products and technologies appear promising during various stages of development, there may not be successful commercial applications developed for them for a number of reasons, including:

- the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), the competent authority of an EU Member State or an institutional review board (IRB), or an Ethics Committee (EU equivalent to IRB), or our pharmaceutical or biotechnology partners may delay or halt applicable clinical trials;
- we or our pharmaceutical or biotechnology partners may face slower than expected rate of patient recruitment and enrollment in clinical trials, or may devote insufficient funding to the clinical trials;
- we or our products and technologies or our pharmaceutical and biotechnology company partners' products may be found to be ineffective or cause harmful side effects, or may fail during any stage of pre-clinical testing or clinical trials;
- we may not find additional pharmaceutical or biotechnology companies to adopt our technologies or, if partnered, the business strategy of our partners may change;
- we or our pharmaceutical and biotechnology company partners may find certain products using our technologies cannot be manufactured on a commercial scale and, therefore, may not be economical to produce;
- we or our partners may determine that managed care providers are unwilling or unable to reimburse patients at an economically attractive level for products under development; or
- products that use our technologies and products in development acquired from Éclat could fail to obtain regulatory approval or, if approved, fail to achieve market acceptance, fail to be included within the pricing and reimbursement schemes of the U.S. or EU Member States, or be precluded from commercialization by proprietary rights of third parties.

We must invest substantial sums in research and development in order to remain competitive, and we may not fully recover these investments.

To be successful in the highly competitive pharmaceutical industry, we must commit substantial resources each year to research and development in order to develop technologies and new products. In 2012, we spent $26.1 million on research and development. Our ongoing investments in research and development for future products could result in higher costs without a proportionate increase, or any increase, in revenues. The research and development process is lengthy and carries a substantial risk of failure. If our research and development does not yield sufficient new technologies and products that achieve commercial success, our future operating results will be adversely affected.

We must comply with various covenants and obligations under a note agreement with Breaking Stick LLC (formerly Éclat Holdings LLC) and a Facility Agreement with Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (Deerfield Entities) and our failure to do so could adversely affect our ability to operate our business, develop our product portfolio or pursue certain opportunities.

We and our subsidiaries are subject to financial and non-financial restrictive covenants under the note agreement with Breaking Stick LLC and facility agreement with the Deerfield Entities that may impair our ability and reduce our flexibility to operate and finance our business, plan for or react to changes in our business, the economy or the markets, or limit our ability to engage in activities that may be in our long term best interest. These covenants include, restrictive covenants with respect to (i) establishment of new subsidiaries, (ii) liquidation, dissolution, mergers, consolidations or other corporate reorganizations, (iii) prior to March 13, 2015, engaging someone other than Mr. Anderson to manage a substantial part of our business, unless Mr. Anderson's employment agreement is terminated before such date other than as a result of our breach, (iv) making restricted payments (such as dividends or distributions) to any shareholder, (v) creating or incurring any lien on our assets or those of our subsidiaries, subject to certain permitted exceptions; and (vi) creating, incurring, assuming or guaranteeing any indebtedness, subject to certain permitted exceptions. If we were to default under the note or facility agreement by violating covenants or otherwise, Breaking Stick's remedies would include the ability to, among other things, accelerate payment of all or a substantial portion of the amounts payable under the note and seize outstanding receivables. Our largest shareholder, Deerfield Capital, has a controlling interest, and our Chief Executive Officer, Mr. Anderson, has a minority interest in Breaking Stick. As a result, their interest may differ from those of our other shareholders. Defaults under the note or facility agreement, if not cured or waived, could have a material adverse effect on our business, financial condition, and results of operations.

We depend upon a single site to manufacture our drug delivery products, and any interruption of operations could have a material adverse effect on our business.

All of our manufacturing for our drug delivery platforms currently takes place in our production facilities located in Pessac, France. A significant interruption of operations at this facility for any reason, such as fire, flood, labor disruptions or other manmade or natural disaster or a failure to obtain or maintain required regulatory approvals, could have a material adverse effect on our business, financial condition and results of operations. In case of a disruption, we may need to establish alternative manufacturing sources for our drug delivery products, and this would likely lead to substantial production delays as we build or locate replacement facilities and seek to satisfy necessary regulatory obligations, including undergoing a successful inspection by the FDA, EMA, the competent authorities of EU Member States or our clients and obtaining the required regulatory approvals with respect to our drug delivery products. If this occurs, we may be unable to demonstrate compliance with applicable regulatory requirements governing manufacturing and to satisfy contractual obligations related to our drug delivery products with our pharmaceutical or biotechnology partners in a timely manner.

We depend on a limited number of suppliers for certain raw materials used in our drug delivery platforms and for the manufacture of certain products in development, and any failure of such suppliers to deliver sufficient quantities of these raw materials or product could interrupt our production process and could have a material adverse affect on our business.

We purchase a number of raw materials used in our drug delivery platforms and products in development from a limited number of suppliers, including a single supplier for certain key ingredients. These raw materials include excipients such as celpheres and cellets and active ingredients such as carvedilol phosphate used for the production of Coreg CR® microparticles and polyglutamate used in the production of our Medusa polymers. We use a contract manufacturing organization for the supply of our products in development. We generally have contracts in place with these suppliers, which are reviewed based on future forecast requirements. We determine minimum inventory levels based on our goal of holding at least three months of future requirements in inventory. If the supplies of these materials were interrupted for any reason, our manufacturing and marketing of certain products could be delayed. These delays could be extensive and expensive, especially in situations where a substitution was not readily available or required variations of existing regulatory approvals and certifications or additional regulatory approval. For example, an alternative supplier may be required to pass an inspection by the FDA, EMA or the competent authorities of EU Member States for compliance with current Good Manufacturing Practices (cGMP) requirements before we may incorporate that supplier's ingredients into our manufacturing. We expect to continue relying on our current suppliers for the foreseeable future, but failure to obtain adequate supplies in a timely manner could have a material adverse effect on our business, financial condition and results of operations.

We depend on key personnel to execute our business plan. If we cannot attract and retain key personnel, we may not be able to successfully implement our business plan.

Our success depends in large part upon our ability to attract and retain highly qualified personnel. During our operating history, we have assigned many key responsibilities within our Company to a relatively small number of individuals, each of whom has played key roles in executing various important components of our business. We do not maintain material key person life insurance for any of our key personnel. If we lose the services of Michael S. Anderson, our Chief Executive Officer, we may have difficulty executing our business plan in the manner we currently anticipate. Further, because each of our key personnel is involved in numerous roles in various components of our business, the loss of any one or more of such individuals could have an adverse effect on our business.

If our competitors develop and market technologies or products that are safer or more effective than ours, or obtain regulatory approval and market such technologies or products before we do, our commercial opportunity will be diminished or eliminated.

Competition in the pharmaceutical and biotechnology industry is intense and is expected to increase. We compete with academic laboratories, research institutions, universities, joint ventures and other pharmaceutical and biotechnology companies, including other companies developing drug delivery platforms. Some of these competitors are also our business partners. Our Medusa technology competes with technologies from companies such as Ambrx, Enzon, Polytherics, or Prolor Biotech. Numerous companies, such as Acusphere, Supernus or Depomed, develop oral drug delivery platform that can compete with our Micropump technology. LiquiTime (liquid oral controlled-delivery platform) competes with technologies such as those developed Tris Pharma. With our Trigger Lock technology, we compete with companies seeking to develop abuse-deterrent formulations of scheduled drugs such as Pain Therapeutics or Acura Pharmaceuticals. The Éclat products compete with products of companies such as Covidien, Hi-Tech, and others. If we are successful in expanding our marketed products, we will encounter more competitors.

Many of these competitors have substantially greater financial, technological, manufacturing, marketing, managerial and research and development resources and experience than we do. Furthermore, acquisitions of competing drug delivery companies by large pharmaceutical companies could enhance our competitors' resources. Accordingly, our competitors may succeed in developing competing technologies and products, obtaining regulatory approval and gaining market share for these products more rapidly than we do.

Additionally, new chemical entities could be developed that, if successful, could compete against our technologies or products. Among the many experimental therapies being tested in the U.S. and in the EU, there may be some that we do not now know of that may compete with our drug delivery platforms or products in the future. These chemical entities and new products may be safer or may work better than our technologies or products. Our collaborators could choose a competing drug delivery platform to use with their drugs instead of one of our drug delivery platforms.

We may fail to realize the anticipated benefits expected from the acquisition of Éclat and its portfolio of pipeline products.

With the acquisition of Éclat, a new part of our business strategy is to grow its existing product, Hycet, and to develop, obtain FDA approval and commercialize its portfolio of potential niche brand and generic specialty pharmaceutical products. We also are aiming to transition to a more vertically integrated business model that adds increased commercial capabilities in the US to our existing drug delivery platforms. There can be no assurance that this strategy will be successful or that we will be able to successfully integrate and grow these two businesses, which could negatively impact our business and operating results.

If we choose to acquire new and complementary businesses, products or technologies, we may be unable to complete these acquisitions or to successfully integrate them in a cost effective and non-disruptive manner.

Our success depends in part on our ability to continually enhance and broaden our product offerings in response to market demands, competitive pressures and evolving technologies. Accordingly, we may in the future pursue the acquisition of complementary businesses, products or technologies instead of developing them ourselves. We do not know if we would be able to successfully complete any acquisitions, or whether we would be able to successfully integrate any acquired business, product or technology or retain any key employees. Integrating any business, product or technology we acquire could be expensive and time consuming, disrupt our ongoing business and distract our management. If we were to be unable to integrate any acquired businesses, products or technologies effectively, our business would suffer. In addition, any amortization or charges resulting from the costs of acquisitions could negatively impact our operating results.

If we cannot keep pace with the rapid technological change in our industry, we may lose business, and our drug delivery platforms could become obsolete or noncompetitive.

Our success also depends, in part, on maintaining a competitive position in the development of products and technologies in a rapidly evolving field. Major technological changes can happen quickly in the biotechnology and pharmaceutical industries. If we cannot maintain competitive products and technologies, our current and potential pharmaceutical and biotechnology company partners may choose to adopt the drug delivery platforms of our competitors. Our competitors may succeed in developing competing technologies or obtaining regulatory approval for products before us, and the products of our competitors may gain market acceptance more rapidly than our products. Such rapid technological change, or the development by our competitors of technologically improved or different products, could render our drug delivery platforms obsolete or noncompetitive.

If we cannot adequately protect our intellectual property and proprietary information, we may be unable to sustain a competitive advantage.

Our success depends, in part, on our ability to obtain and enforce patents for our products, processes and technologies and to preserve our trade secrets and other proprietary information. If we cannot do so, our competitors may exploit our innovations and deprive us of the ability to realize revenues and profits from our developments.

Any patent applications that we may have made or may make relating to our potential products, processes and technologies may not result in patents being issued. Patent law relating to the scope of claims in the pharmaceutical field in which we operate is continually evolving and can be the subject of some uncertainty. The laws providing patent protection may change in a way that would limit protection. Our current patents may not be exclusive, valid or enforceable. They may not protect us against competitors that challenge our patents, such as companies that submit drug marketing applications to the FDA, the EMA, or the competent authorities of EU Member States that rely, at least in part, on safety and efficacy data from our products or our business partners' products (e.g., abbreviated new drug applications), obtain patents that may have an adverse effect on our ability to conduct business or are able to circumvent our patents. The scope of any patent protection may not be sufficiently broad to cover our products or to exclude competing products. Our collaborations with third parties expose us to risks that they will claim intellectual property rights on our inventions or fail to keep our unpatented technology confidential.

We may not have the necessary financial resources to enforce our patents. Further, patent protection once obtained is limited in time, after which competitors may use the covered technology without obtaining a license from us. Because of the time required to obtain regulatory marketing approval, the period of effective patent protection for a marketed product is frequently substantially shortened.

We also rely on trademarks, copyrights, trade secrets and know-how to develop, maintain and strengthen our competitive position. To protect our trade secrets and proprietary technologies and processes, we rely, in part, on confidentiality agreements with our employees, consultants, advisors and partners. These agreements may not provide adequate protection for our trade secrets and other proprietary information in the event of any unauthorized use or disclosure, or if others lawfully develop the information. If these agreements are breached, we cannot be certain that we will have adequate remedies. Further, we cannot guarantee that third parties will not know, discover or independently develop equivalent proprietary information or techniques, or that they will not gain access to our trade secrets or disclose our trade secrets to the public. Therefore, we cannot guarantee that we can maintain and protect unpatented proprietary information and trade secrets. Misappropriation or other loss of our intellectual property would adversely affect our competitive position and may cause us to incur substantial litigation or other costs.

The implementation of the Leahy-Smith America Invents Act of 2011 may adversely affect our business.

The Leahy-Smith America Invents Act of 2011 (AIA), which was signed into law on September 16, 2011, includes several provisions that may impact our business and patent protection in the United States. The AIA changes the current U.S. “first-to-invent” system to a system that awards a patent to the “first-inventor-to-file” for an application for a patentable invention. This change alters the pool of available materials that can be used to challenge patents in the U.S. and eliminates the ability to rely on prior research to lay claim to patent rights. Disputes will be resolved through new derivation proceedings and the AIA creates mechanisms to allow challenges to newly issued patents in reexamination proceedings. Although many of the changes bring U.S. law into closer harmony with EU and other national patent laws, the new bases and procedures may make it easier for competitors to challenge our patents, which could result in increased competition and have a material adverse effect on our business and results of operations. The changes may also make it harder to challenge third-party patents and place greater importance on being the first inventor to file a patent application on an invention. The AIA amendments to patent filing and litigation procedures in the U.S., may result in litigation being more complex and expensive and divert the efforts of our technical and management personnel.

Even if we and our partners obtain necessary regulatory approvals, their and our products and our technologies may not gain market acceptance.

Even if we and our pharmaceutical and biotechnology company partners obtain the necessary regulatory approval to market products or products that incorporate our technologies, such products, technologies and product candidates may not gain market acceptance among physicians, patients, healthcare payers and medical communities. The degree of market acceptance of any product, technology or product candidate will depend on a number of factors, including:

- the scope of regulatory approvals, including limitations or warnings in a product’s regulatory-approved labeling;
- demonstration of the clinical efficacy and safety of the product or technology;
- the absence of evidence of undesirable side effects that delay or extend trials;
- the lack of regulatory delays or other regulatory actions;
- its cost-effectiveness;
- its potential advantage over alternative treatment methods;
- the availability of third-party reimbursement; and
- the marketing and distribution support it receives.

If any of our products or technologies or our partners’ products fail to achieve market acceptance, our ability to generate revenue will be limited, which would have a material adverse effect on our business.

Our collaborative arrangements may give rise to disputes over commercial terms, contract interpretation and ownership of our intellectual property and may adversely affect the commercial success of our products.

Our business continues to be dependent on our ability to work with customers and partners in collaborative relationships to develop products using our technologies, although we have products in development that are not dependent on these collaborative relationships.. We have in the past and expect that in the future we will enter into collaborative arrangements, some of which not evidenced by formal or executed definitive agreements, but rather by memoranda of understanding, material transfer agreements, options or feasibility agreements. If the collaborative relationships give rise to disputes regarding the relative rights, obligations and revenues of the parties, including the ownership of intellectual property and associated rights and obligations, such disputes may delay collaborative research, development or commercialization of potential products and may lead to lengthy and expensive litigation or arbitration. The terms of collaborative arrangements may also limit or preclude us from fully developing our products or technologies developed pursuant to such collaborations. Additionally, the collaborators under these arrangements may breach the terms of their respective agreements or fail to prevent infringement of the licensed patents by third parties. Moreover, negotiating collaborative arrangements often takes considerably longer to conclude than the parties initially anticipate, which could cause us to agree to less favorable agreement terms that delay or defer recovery of our development costs and reduce the funding available to support key programs or the development of our products and technologies.

We may be unable to enter into future collaborative arrangements on acceptable terms, which could also adversely affect our ability to develop and commercialize our current and potential future products. Further, even if we do enter into acceptable collaboration arrangements, it is possible that our collaborative partners may not choose to develop and commercialize products using our technologies or may not devote sufficient resources to the development and commercial sales of products using our technologies. Our collaborative arrangements may also limit or preclude us with respect to the development of our products or technologies that may compete with those of our collaborators, but may not necessarily restrict our collaborative partners from competing with us or restrict their ability to market or sell competitive products. Our current and any future collaborative partners may pursue existing or other development-stage products or alternative technologies in preference to those being developed in collaboration with us or may terminate their relationships with us or otherwise decide not to proceed with development and commercialization of products containing our drug delivery platform.

If we or our collaborative partners are required to obtain licenses from third parties, our revenues and royalties on any commercialized products could be reduced.

The development of some of our products may require the use of technology developed by third parties. The extent to which efforts by other researchers have resulted or will result in patents and the extent to which we or our collaborative partners are forced to obtain licenses from others, if available, on commercially reasonable terms is currently unknown. If we or our collaborative partners must obtain licenses from third parties, fees must be paid for such licenses, which would reduce the revenues and royalties we may receive on commercialized products that incorporate our technologies.

Third parties may claim, that our technologies, or the products in which they are used, or our products infringe on their rights, and we may incur significant costs resolving these claims.

Third parties may claim, that the manufacture, use, import, offer for sale or sale of our drug delivery platforms or our products infringes on their patent rights. In response to such claims, we may have to seek licenses, defend infringement actions or challenge the validity of those patent rights in court. If we cannot obtain required licenses, are found liable for infringement or are not able to have such patent rights declared invalid, we may be liable for significant monetary damages, encounter significant delays in bringing products to market or be precluded from the manufacture, use, import, offer for sale or sale of products or methods of drug delivery covered by the patents of others. We may not have identified, or be able to identify in the future, U.S. or foreign patents that pose a risk of potential infringement claims.

Any claims that our products or technologies infringe or may infringe proprietary rights of third parties, with or without merit, could be time-consuming, result in costly litigation or divert the efforts of our technical and management personnel, any of which could disrupt our relationships with our partners and could significantly harm our operating results.

We enter into collaborative agreements with pharmaceutical and biotechnology companies to apply our drug delivery platforms to drugs developed by others. Ultimately, we receive license revenues and product development fees, as well as revenues from royalties and the sale of products incorporating our technology. The drugs to which our drug delivery platforms are applied are generally the property of our pharmaceutical and biotechnology company partners. Those drugs may be the subject of patents or patent applications and other forms of protection owned by such companies or third parties. If those patents or other forms of protection expire, are challenged or become ineffective, sales of the drugs by such companies may be restricted or may cease and adversely affect our revenues.

If our third party collaborative partners face generic competition for their products, our revenues and royalties from such products may be adversely affected.

Some of our third party collaborative partners may utilize our drug delivery platforms in products with exclusive rights secured by patents or other means. These rights are limited in time and do not always provide effective protection for their products. If our collaborative partners are unable to protect their products' exclusivity or patent rights, generic competition may erode their market share, undermine the profitability of their products and limit the royalties we could collect from product sales. The expiration of the Hatch Waxman exclusivity for Coreg CR in April 2010 opens Coreg CR to potential generic competition, which may negatively affect the royalties we could collect in the future. Abbreviated New Drug Applications (ANDA) have been submitted to the FDA by Mutual Pharmaceuticals, Lupin Pharmaceuticals and Impax Laboratories requesting marketing approval of generic formulations of Coreg CR and by Anchen Pharmaceuticals regarding only 40 mg dosage strength. Should the FDA grant approval to either or both of these applications, our royalty income from sales of Coreg CR would be negatively affected (See Item 4 – Information on the Company – General Overview). To date, we have generated $49.4 million in royalty revenue from Coreg CR, the only product sold using our drug delivery platform.

Healthcare reform and restrictions on reimbursements may limit our financial returns.

Our ability to successfully commercialize our products and technologies may depend on the extent to which the government health administration authorities, the health insurance funds in the EU Member States, private health insurers and other third party payers in the U.S. will reimburse consumers for the cost of these products, which would affect the volume of drug products sold by pharmaceutical and biotechnology companies that incorporate our technology into their products. Third party payers are increasingly challenging both the need for, and the price of, novel therapeutic drugs and uncertainty exists as to the reimbursement status of newly approved therapeutics. The commercial success of our products depends in part on the conditions under which products incorporating our technology are reimbursed. Adequate third party reimbursement may not be available for such drug products to enable us to maintain price levels sufficient to realize an appropriate return on our investments in research and product development, which could materially and adversely affect our business. We cannot predict the effect that changes in the healthcare system, especially cost containment efforts, may have on our business. In particular, it is difficult to predict the effect of health care reform legislation enacted in the U.S. in 2010, certain provisions of which are still subject to regulatory implementation, further legislative change and ongoing judicial review. Any such changes or changes due to future legislation governing the pricing and reimbursement of healthcare products in the EU Member States may adversely affect our business.

Security breaches and other disruptions could compromise confidential information and expose us to liability and cause our business and reputation to suffer.

In the ordinary course of our business, we collect and store proprietary data, including intellectual property, our proprietary business information and that of our customers, suppliers and business partners, on our networks. The secure maintenance and transmission of this information is critical to our operations and business strategy. Despite our security measures, our information systems and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, investigations by regulatory authorities in the U.S. and EU Member States, disruption to our operations and damage to our reputation, any of which could adversely affect our business.

Failure to comply with domestic and international privacy and security laws could result in the imposition of significant civil and criminal penalties.

The costs of compliance with these laws, including protecting electronically stored information from cyber attacks, and potential liability associated with failure to do so could adversely affect our business, financial condition and results of operations. We are subject to various domestic and international privacy and security regulations, including but not limited to The Health Insurance Portability and Accountability Act of 1996 (HIPAA). HIPAA mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. In addition, many states have enacted comparable laws addressing the privacy and security of health information, some of which are more stringent than HIPAA.

Fluctuations in foreign currency exchange rates and the impact of the European sovereign debt crisis may cause fluctuations in our financial results.

For the year ended December 31, 2012, we derived 42% of our total revenues from transactions in U.S. dollars, but have 34% of our cash and cash equivalents, all of our marketable securities, and the majority of our expenses denominated in Euros. Our functional currency is the Euro and our reporting currency is the U.S. Dollar. As a result, both our actual and reported financial results could be significantly affected by fluctuations of the Euro relative to the U.S. dollar. We do not engage in substantial hedging activities with respect to the risk of exchange rate fluctuations, although we do, from time to time, purchase Euros against invoiced Dollar receivables.

Recent developments in the EU have created uncertainty about the ability of certain EU Member States to continue to service their sovereign debt obligations. This debt crisis and the related financial restructuring efforts may cause the value of the Euro to deteriorate, reducing the value of the Euro relative to the U.S. Dollar. Any strengthening in the U.S. Dollar relative to the Euro would have a negative effect on our balance sheet while a weakening in the U.S. Dollar relative to the Euro would have a positive effect. See ‘Quantitative and Qualitative Disclosures About Market Risk’ on page 75 for more information on the impact of currency exchange rate fluctuations. In addition, the sovereign debt crisis affecting some EU Member States is contributing to instability in global credit markets. If global economic and market conditions, or economic conditions in the European Union, the U.S. or other key markets, remain uncertain, persist or deteriorate further, our business, financial condition, results of operations and cash flows may be adversely affected.

Risks Relating to Regulatory and Legal Matters

Products that incorporate our drug delivery platforms and our development products acquired from Éclat and other products we may develop are subject to regulatory approval. If we or our pharmaceutical and biotechnology company partners do not obtain such approvals, or if such approvals are delayed, our revenues may be adversely affected.

In the U.S., federal state and local government agencies, primarily the FDA, regulate all pharmaceutical products, including existing products and those under development. We or our pharmaceutical and biotechnology company partners may experience significant delays in expected product releases while attempting to obtain regulatory approval for products incorporating our technologies. If we or our partners are not successful, our revenues and profitability may decline. We cannot control, and our pharmaceutical and biotechnology company partners cannot control, the timing of regulatory approval for any of these products, or if approval is obtained at all.

Applicants for FDA approval often must submit to the FDA extensive clinical and pre-clinical data as well as information about product manufacturing processes and facilities and other supporting information. Varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of a drug product. The FDA also may require us or our partners to conduct additional pre-clinical studies or clinical trials. For instance, we do not anticipate the necessity to conduct individual toxicity and carcinogenicity tests for each product that we develop using the Medusa nano-particulate technology. Due to their special properties, however, nanoparticle formulations may pose different issues of safety or effectiveness than non-nanoscale products. With that in mind, the FDA may require additional toxicology tests and clinical trials to confirm the safety and effectiveness of product candidates using the Medusa technology, which would impact development plans for product candidates. Similarly, although we anticipate submitting applications for approval for the development products acquired from Éclat that rely on existing data to demonstrate safety and effectiveness, FDA may determine that additional studies particular to our products are necessary. If FDA requires such additional data, it would impact development plans for those products.

Changes in FDA approval policy during the development period, or changes in regulatory review for each submitted new product application, also may delay an approval or result in rejection of an application. For instance, under the Food and Drug Administration Amendments Act of 2007 (FDAAA), we or our partners may be required to develop risk evaluations and mitigation strategies, or REMS, to ensure the safe use of their product candidates. If the FDA disagrees with our or our partners' REMS proposals, it may be more difficult and costly for us or our partners to obtain regulatory approval for product candidates. Similarly, FDAAA provisions may make it more likely that the FDA will refer a marketing application for a new product to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. This review may add to the wait time for approval, and, although the FDA is not bound by the recommendation of an advisory committee, objections or concerns expressed by an advisory committee may cause the FDA to delay or deny approval.

The FDA has substantial discretion in the approval process and may disagree with our or our partners' interpretations of data and information submitted in an application, which also could cause delays of an approval or rejection of an application. Even if the FDA approves a product, the approval may limit the uses or indications for which a product may be marketed, restrict distribution of the product or require further studies.

The FDA may also withdraw product clearances and approvals for failure to comply with regulatory requirements or if problems follow initial marketing. In the same way, medicinal products for supply on the EU market are subject to marketing authorization by either the European Commission, following an opinion by the EMA, or by the competent authorities of EU Member States. Applicants for marketing authorization must submit extensive technical and clinical data essentially in the form of the ICH Common Technical Document. The data is subject to extensive review by the competent authorities and may be considered inappropriate or insufficient. If applications for marketing authorization by pharmaceutical and biotechnology company partners are delayed, or rejected, if the therapeutic indications for which the product is approved are limited, or if conditional marketing authorization imposing post-marketing clinical trials or surveillance is imposed, our revenues may decline and earnings may be negatively impacted.

Manufacturers of drugs, including the active pharmaceutical ingredients, also must comply with applicable cGMP requirements, both as a condition of approval and for continued authority to manufacture and distribute products. Our manufacturing facilities and those of our pharmaceutical and biotechnology company partners may be required to pass a pre-approval inspection by the FDA, the EMA, the competent authorities of EU Member States or our customers, and will be subject to periodic inspection after that, all intended to ensure compliance with cGMP. The cGMP requirements govern quality control of the manufacturing process and documentation policies and procedures, and we and our pharmaceutical and biotechnology company partners will need to ensure that all of our processes, methods and equipment are compliant with cGMP. We will be obligated to expend time, money and effort in production, record keeping and quality control to assure that the product meets applicable specifications and other requirements. If we, our pharmaceutical and biotechnology company partners or suppliers of key ingredients cannot comply with these practices, the sale of our products or products developed by our partners that incorporate our technologies may be suspended. This would reduce our revenues and gross profits.

If our products or products that incorporate our technologies are marketed in other jurisdictions, we and the partners with whom we are developing our technologies must obtain required regulatory approvals from foreign regulatory agencies and comply with extensive regulations regarding safety, quality and efficacy. These related obligations are frequently as demanding as those imposed by the FDA, the EMA or the competent authorities of EU Member States. If approvals to market our products or our partners' products are delayed, or if we or our partners fail to receive these approvals or previously received approvals are withdrawn, our revenues would be reduced. We may be required to incur significant costs to obtain or maintain foreign regulatory approvals.

Commercial products are subject to continuing regulation, and we on our own, and in conjunction with our pharmaceutical and biotechnology company partners, may be subject to adverse consequences if we or they fail to comply with applicable regulations.

We on our own and in conjunction with our pharmaceutical and biotechnology company partners will be subject to extensive regulatory requirements for our and their products and product candidates that incorporate our technologies, even if the products receive regulatory approval. These regulations are wide-ranging and govern, among other things:

- adverse drug experiences and other reporting requirements;
- product promotion and marketing;
- product manufacturing, including cGMP compliance;
- record keeping;
- distribution of drug samples;
- required post-marketing studies or clinical trials;
- authorization renewal procedures;
- authorization variation procedures;
- compliance with any required REMS;
- updating safety and efficacy information;
- processing of personal data;
- use of electronic records and signatures; and
- changes to product manufacturing or labeling.

If we or our partners, including any contract manufacturers that we use, fail to comply with these laws and regulations, the FDA, the European Commission, competent authorities of EU Member States, or other regulatory organizations, may take actions that could significantly restrict or prohibit commercial distribution of our products and products that incorporate our technologies. If the FDA, the European Commission or competent authorities of EU Member States determine that we are not in compliance with these laws and regulations, they could, among other things:

- issue warning letters;
- impose fines;
- seize products or request or order recalls;
- issue injunctions to stop future sales of products;
- refuse to permit products to be imported into, or exported out of, the United States or the European Union;
- suspend or limit our production;
- withdraw or vary approval of marketing applications;
- order the competent authorities of EU Member States to withdraw or vary national authorization; and
- initiate criminal prosecutions.

We are subject to U.S. federal and state laws prohibiting "kickbacks" and false claims that, if violated, could subject us to substantial penalties, and any challenges to or investigation into our practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm our business.

We are subject to extensive and complex U.S. federal and state and international laws and regulations, including but not limited to, health care "fraud and abuse" laws, such as anti-kickback and false claims laws and regulations pertaining to government benefit program reimbursement, price reporting and regulations, and sales and marketing practices. These laws and regulations are broad in scope and they are subject to evolving interpretations, which could require us to incur substantial costs associated with compliance or to alter one or more of our sales or marketing practices. In addition, violations of these laws, or allegations of such violations, could disrupt our business and result in a material adverse effect on our revenues, profitability, and financial condition. In the current environment, there appears to be a greater risk of investigations of possible violations of these laws and regulations. This is reflected by recent enforcement activity and pronouncements by the US Office of Inspector General of the Department of Health and Human Services that it intends to continue to vigorously pursue fraud and abuse violations by pharmaceutical companies, including through the potential to impose criminal penalties on pharmaceutical company executives. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Regulatory reforms may adversely affect our ability to sell our products or technologies profitably.

From time to time, the US Congress, the Council of the European Union and the European Parliament, as well as the legislators of the EU Member States, adopt changes to the statutes that the FDA, the European Commission and the competent authorities of the EU Member States enforce in ways that could significantly affect our business. In addition, the FDA, the European Commission and the competent authorities of the EU Member States often issue new regulations or guidance, or revise or reinterpret their current regulations and guidance in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted or FDA, EU or EU Member State's regulations, guidance or interpretations changed, and what the impact of any such changes may be.

It is possible, however, that such changes could have a significant impact on the path to approval of products incorporating our technologies, our products or of competing products, and to our obligations and those of our pharmaceutical and biotechnology company partners. For example, the FDAAA contains a number of provisions that strengthen the FDA's regulatory authority in various areas, including clinical trial registration and results reporting, pharmacovigilance, quality and other safety-related issues and post-approval clinical study requirements. As another example, with adoption of the Biologics Price Competition and Innovation Act of 2009 (BPCIA), enacted in March, 2010 as a subtitle of the Patient Protection and Affordable Care Act, biological products incorporating our technologies may face competition from "biosimilar" products that are approved via an abbreviated process on the basis of a showing that the product is highly similar to the approved product. This abbreviated approval pathway is intended to permit a biosimilar product to come to market more quickly and less expensively than if a "full" biologics license application (BLA) were submitted, by relying to some extent on FDA's previous review and approval of the reference product to which the proposed product is similar. The BPCIA provides periods of exclusivity during which abbreviated applications may not be submitted to, or approved by, FDA, but the statute then allows approval by an abbreviated pathway and, if certain standards are met, a finding by FDA that the biosimilar product is interchangeable with the reference product. If competitors are able to obtain marketing approval for biosimilars under an abbreviated regulatory approval process in the U.S. or the EU, certain products incorporating our technologies may become subject to additional competition with the attendant pricing pressure. Because the BPCIA is a highly complicated statute that has only recently been enacted, there is uncertainty as to how many important components of the new law will be implemented. Some issues may be resolved by three draft guidances that FDA issued in February 2012 or by issuance of regulations or other guidances, but other positions may develop on an ad hoc basis as FDA confronts them in the context of specific applications. The recent modifications to the provisions of the Community Code on medicinal product governing pharmacovigilance also impose further reporting and surveillance obligations on our partner pharmaceutical and biotechnology companies and grant greater supervisory powers to the European Commission and the competent authorities of EU Member States.

We and companies to which we have licensed our technology and subcontractors we engage for services related to our in development products are subject to extensive regulation by the FDA and other regulatory authorities. Our and their failure to meet strict regulatory requirements could adversely affect our business.

We and companies to which we license our technology as well as companies acting as subcontractors for our products are subject to extensive regulation by the FDA, other domestic regulatory authorities and equivalent foreign regulatory authorities, particularly the European Commission and the competent authorities of EU Member States. Those regulatory authorities may conduct periodic audits or inspections of the applicable facilities to monitor compliance with regulatory standards and we remain responsible for the compliance of our subcontractors. If the FDA or another regulatory authority finds failure to comply with applicable regulations, the authority may institute a wide variety of enforcement actions, including: warning letters or untitled letters; fines and civil penalties; delays in clearing or approving, or refusal to clear or approve, products; withdrawal, suspension or variation of approval of products; product recall or seizure; orders to the competent authorities of EU Member States to withdraw or vary national authorization; orders for physician notification or device repair, replacement or refund; interruption of production; operating restrictions; injunctions; and criminal prosecution. Any adverse action by a competent regulatory agency could lead to unanticipated expenditures to address or defend such action and may impair the ability to produce and market applicable products, which could significantly impact our revenues and royalties that we receive from our customers.

We may face product liability claims related to clinical trials we may sponsor or for which we provide investigational products or technologies or the use or misuse of our products or products that incorporate our technologies.

The testing, including through clinical trials, manufacturing and marketing of our products or products that incorporate our drug delivery platforms may expose us to potential product liability and other claims resulting from their use. If any such claims against us are successful, we may be required to make significant compensation payments. Any indemnification that we have obtained, or may obtain, from contract research organizations or pharmaceutical and biotechnology companies or hospitals conducting human clinical trials on our behalf may not protect us from product liability claims or from the costs of related litigation. Insurance coverage is expensive and difficult to obtain, and we may be unable to obtain coverage in the future on acceptable terms, if at all. Although we currently maintain general liability insurance with a limit of €8 million and product liability and recall insurance with a limit of €10 million for products incorporating our technology, and coverage of $5 million for products marketed by Éclat. We believe the amounts to be commercially reasonable, we cannot be certain that the coverage limits of our insurance policies or those of our strategic partners will be adequate. If we are unable to obtain sufficient insurance at an acceptable cost, a product liability claim or recall could adversely affect our financial condition. Similarly, any indemnification we have obtained, or may obtain, from pharmaceutical and biotechnology companies with whom we are developing our drug delivery platforms may not protect us from product liability claims from the consumers of those products or from the costs of related litigation. If we are subject to a product liability claim, our product liability insurance may not reimburse us, or be sufficient to reimburse us, for any expenses or losses we may suffer. A successful product liability claim against us, if not covered by, or if in excess of, our product liability insurance, may require us to make significant compensation payments. These payments would be reflected as expenses on our statement of operations and reduce our earnings.

If we use biological and hazardous materials in a manner that causes injury, we may be liable for significant damages.

Our research and development activities involve the controlled use of potentially harmful biological materials, hazardous materials and chemicals, and are subject to U.S., state, EU, national and local laws and regulations governing the use, storage, handling and disposal of those materials and specified waste products. We cannot completely eliminate the risk of accidental contamination or injury from the use, storage, handling or disposal of these materials, including fires and/or explosions, storage tank leaks and ruptures and discharges or releases of toxic or hazardous substances. These operating risks can cause personal injury, property damage and environmental contamination, and may result in the shutdown of affected facilities and the imposition of civil or criminal penalties. The occurrence of any of these events may significantly reduce the productivity and profitability of a particular manufacturing facility and adversely affect our operating results.

We currently maintain environmental liability, property, business interruption and casualty insurance with aggregate maximum limits of €115 million, which are limits that we believe to be commercially reasonable, but may be inadequate to cover any actual liability or damages. If we fail to comply with environmental regulations, we could be subject to criminal sanctions and/or substantial liability for any damages that result, and any such liability could be significant.

Risks Relating to Ownership of Our Securities

Our share price has been volatile and may continue to be volatile.

The trading price of our shares has been, and is likely to continue to be, highly volatile. The market value of an investment in our shares may fall sharply at any time due to this volatility. During the year ended December 31, 2012, the closing sale price of our ADSs as reported on the NASDAQ National Market ranged from $2.99 to $7.67. During the year ended December 31, 2011, the closing sale price of our ADSs as reported on the NASDAQ National Market ranged from $3.85 to $6.97. The market prices for securities of drug delivery, biotechnology and pharmaceutical companies historically have been highly volatile. Factors that could adversely affect our share price include, among others:

- fluctuations in our operating results;
- announcements of technological collaborations, innovations or new products by us or our competitors;
- actions with respect to the acquisition of new or complementary businesses;
- governmental regulations;
- developments in patent or other proprietary rights owned by us or others;
- public concern as to the safety of drug delivery platforms developed by us or drugs developed by others using our platform;
- the results of pre-clinical testing and clinical studies or trials by us or our competitors;
- adverse events related to our products or products developed by pharmaceutical and biotechnology company partners that use our drug delivery platforms;
- lack of efficacy of our products;
- litigation;
- decisions by our pharmaceutical and biotechnology company partners relating to the products incorporating our technologies;
- actions by the FDA, the EMA or national authorities of EU Member States in connection with submissions related to the products incorporating our technologies;
- the perception by the market of biotechnology and high technology companies generally; and
- general market conditions, including the impact of the current financial environment.

Because we have limited commercial sales, evaluating our prospects may be difficult.

We recorded the first commercial sales of products using one of our polymer technologies through our partner, Corning, in 1999. Our first commercial sales of a pharmaceutical compound incorporating our Micropump technology occurred in March 2007 with the launch of Coreg CR. We have had no commercial sales to date of products incorporating our Medusa technology. Accordingly, we have only a limited history of commercial sales, which may make it difficult to evaluate our prospects. The difficulty in evaluating our prospects may cause volatile fluctuations in the market price of our shares as investors and holders react to information about our prospects. Since 1995, we have generated revenues from product development fees and licensing arrangements and royalties. Our business and prospects must be evaluated in light of the risks and uncertainties of a company with limited commercial sales of products and only two currently marketed products, one of which, Hycet, we consider a niche product.

If we are not profitable in the future, the value of our shares may fall.

We have a history of operating losses and have accumulated aggregate net loss from inception of approximately $193 million through December 31, 2012. If we are unable to earn a profit in future periods, the market price of our stock may fall. The costs for research and product development of our drug delivery platforms and general and administrative expenses have been the principal causes of our net losses in recent years. Our ability to operate profitably depends upon a number of factors, many of which are beyond our direct control. These factors include:

- the demand for our technologies and products;
- the level of product and price competition;
- our ability to develop new collaborative partnerships and additional commercial applications for our products;
- our ability to control our costs;
- our ability to broaden our customer base;
- the effectiveness of our marketing strategy;
- the effectiveness of our partners' marketing strategy for products that use our technology; and
- general economic conditions.

We may require additional financing, which may not be available on favorable terms or at all, and which may result in dilution of our shareholders' equity interest.

We may require additional financing to fund the development and possible acquisition of new drug products and delivery platforms and to increase our production capacity beyond what is currently anticipated. We may consume available resources more rapidly than currently anticipated, resulting in the need for additional funding. If we cannot obtain financing when needed, or obtain it on favorable terms, we may be required to curtail our plans to continue to develop drug delivery platforms . We also may elect to pursue additional financing at any time to more aggressively pursue development of new drug delivery platforms . Other factors that will affect future capital requirements and may require us to seek additional financing include:

- the development and acquisition of new products and technologies;
- the progress of our research and product development programs;
- results of our collaborative efforts with current and potential pharmaceutical and biotechnology company partners; and
- the timing of, and amounts received from, future product sales, product development fees and licensing revenue and royalties.

If adequate funds are not available, we may be required to significantly reduce or refocus our product development efforts, resulting in loss of sales, increased costs and reduced revenues.

Our operating results may fluctuate, which may adversely affect our share price.

Fluctuations in our operating results may lead to fluctuations, including declines, in our share price. Our operating results may fluctuate from period to period due to a variety of factors, including:

- demand by consumers for the products we and our partners produce;
- new product introductions;
- pharmaceutical and biotechnology company ordering patterns;
- the number of new collaborative agreements into which we enter;
- the number and timing of product development milestones that we achieve under collaborative agreements;

- the level of our development activity conducted for, and at the direction of, pharmaceutical and biotechnology companies under collaborative agreements; and

- the level of our spending on new drug delivery platform development and technology acquisition, and internal product development.

Variations in the timing of our revenue and expenses also could cause significant fluctuations in our operating results from period to period and may result in greater than expected losses or more difficulty achieving earnings.

We are subject to different corporate disclosure standards that may limit the information available to holders of our ADSs.

As a foreign private issuer, we are not required to comply with the notice and disclosure requirements under the Exchange Act, relating to the solicitation of proxies for shareholder meetings. Although we are subject to the periodic reporting requirements of the Exchange Act, the periodic disclosure required of non-U.S. issuers under the Exchange Act is more limited than the periodic disclosure required of U.S. issuers. Therefore, there may be less publicly available information about us than is regularly published by or about other public companies in the United States.

We currently do not intend to pay dividends and cannot assure shareholders that we will make dividend payments in the future.

We have never declared or paid a cash dividend on any of our capital stock and do not anticipate declaring cash dividends in the foreseeable future. Declaration of dividends on our shares will depend upon, among other things, future earnings, if any, the operating and financial condition of our business, our capital requirements, general business conditions and such other factors as our Board of Directors deems relevant.

Judgments of United States courts, including those predicated on the civil liability provisions of the federal securities laws of the United States, may not be enforceable in French courts.

An investor in the U.S. may find it difficult to:

- effect service of process within the U.S. against us and our non-U.S. resident directors and officers;

- enforce United States court judgments based upon the civil liability provisions of the United States federal securities laws against us and our non-U.S. resident directors and officers in France; or

- bring an original action in a French court to enforce liabilities based upon the U.S. federal securities laws against us and our non-U.S. resident directors and officers.

Holders of ADSs have fewer rights than shareholders and have to act through the Depositary to exercise those rights.

Holders of ADSs do not have the same rights as shareholders and, accordingly, cannot exercise rights of shareholders against us. The Bank of New York Mellon, as depositary, or the “Depositary”, is the registered shareholder of the deposited shares underlying the ADSs. Therefore, holders of ADSs will generally have to exercise the rights attached to those shares through the Depositary. We will use reasonable efforts to request that the Depositary notify the holders of ADSs of upcoming votes and ask for voting instructions from them. If a holder fails to return a voting instruction card to the Depositary by the date established by the Depositary for receipt of such voting instructions, or if the Depositary receives an improperly completed or blank voting instruction card, or if the voting instructions included in the voting instruction card are illegible or unclear, then such holder will be deemed to have instructed the Depositary to vote its shares, and the Depositary shall vote such shares in favor of any resolution proposed or approved by our Board of Directors and against any resolution not so proposed or approved.

Preferential subscription rights may not be available for U.S. persons.

Under French law, shareholders have preferential rights to subscribe for cash issuances of new shares or other securities giving rights to acquire additional shares on a pro rata basis. U.S. holders of our securities (which might not be shares but ADRs) may not be able to exercise preferential subscription rights for their securities unless a registration statement under the Securities Act is effective with respect to such rights or an exemption from the registration requirements imposed by the Securities Act is available. We may, from time to time, issue new shares or other securities giving rights to acquire additional shares (such as warrants) at a time when no registration statement is in effect and no Securities Act exemption is available. If so, United States holders of our securities will be unable to exercise any preferential rights and their interests will be diluted. We are under no obligation to file any registration statement in connection with any issuance of new shares or other securities.

For holders of our shares in the form of ADSs, the Depositary may make these rights or other distributions available to holders in the United States if we instruct it to do so. If we fail to issue such instruction and the Depositary determines that it is impractical to sell the rights, it may allow these rights to lapse. In that case, the holders will receive no value for them.

Our largest shareholders own a significant percentage of the share capital and voting rights of the Company.

At March 31, 2013, Deerfield Capital and certain of its affiliates beneficially owned approximately 17.0% of our ADRs, Broadfin Capital. and certain of its affiliates beneficially owned approximately 9.8% of our ADRs. See “Item 7. Major Shareholders and Related Party Transactions — A. Major Shareholders.” To the extent these shareholders continue to hold a large percentage of our share capital and voting rights, they will remain in a position to exert heightened influence in the election of the directors of the Company and in other corporate actions that require shareholder approval, including change of control transactions.

ITEM 4. Information on the Company

General Overview

Flamel Technologies is a specialty pharmaceutical company with a long history of expertise in drug delivery, focusing on the development of safer and more efficacious formulations, tackling unmet medical needs in the process. We are focusing on (1) the development and licensing of five versatile, proprietary drug delivery platforms (2) the development of novel, high-value products based on our drug delivery platforms and (3) as a result of our acquisition of Éclat Pharmaceuticals, LLC, or Éclat, the development, approval, and commercialization of niche branded and generic pharmaceutical products in the U.S.

The Company's versatile, proprietary drug delivery platforms are appropriate for more effectively and safely administering medicines to patients. Our Medusa technology (including, but not limited to its polymers and variants) may be used to solve threshold issues for injectable drugs, such as solubility issues, aggragation issues, or issues relating to poor stability of the protein, peptide, or even small molecules. Delivax incorporates the basic Medusa technology in addressing issues associated with vaccines. Micropump is a technology that allows for the modified release of solid, oral dosage forms. Derivatives of Micropump include TriggerLock, which allows tamper-resistant controlled release formulations of drugs susceptible to abuse and LiquiTime which allows the modified release of liquid medicines.

Our Business Model

As a result of our acquisition of Éclat in March 2012, we have implemented an altered business model allowing the Company to blend novel, high-value internally developed products with its leading drug delivery capabilities and to commercialize niche branded and generic pharmaceutical products in the U.S. By adopting this revised strategy, the company becomes less dependent in the future on the often, changing strategies of its partners. Flamel Technologies is still exploring development, supply and licensing opportunities for its five drug delivery platforms with third parties, but will not rely completely on those partnerships to create revenue and profit opportunities,

The addition of Éclat Pharmaceuticals, acquired in March 2012, brings with it one licensed and marketed product, Hycet® (hydrocodone acetaminophen oral solution), and its generic equivalent, and a product portfolio in various stages of development. . This creates a more vertically integrated business model. Éclat, which has focused on pursuing FDA approvals through the 505(b)(2) mechanism (see *Item 4; Information on the Company – New Drug and Biological Product Development and Approval Process – Patent Restoration and Exclusivity*), adds marketing and licensing knowledge of the commercial and regulatory process in the U.S., which we believe will enhance the ability of the Company to identify potential product candidates for development, leverage new opportunities for the application of our drug delivery platforms, and to license and market products in the United States.

Recent Developments

In March 2012, we acquired, through our wholly owned subsidiary, Flamel US Holdings, Inc., or Flamel US, all of the membership interests of Éclat from Éclat Holdings, LLC, or Éclat Holdings, an affiliate of our largest shareholder Deerfield Capital L.P. Éclat is a St. Louis-based specialty pharmaceutical company focused on the development, approval, and commercialization of niche branded and generic pharmaceutical products. Éclat has one FDA-approved product on the market in the U.S., Hycet®, as well as a portfolioof products in various stages of development. See *Item 4. Information on the Company – General Overview - Acquisition of Éclat Pharmaceuticals, Item 7. Major Shareholders and Related Party Transactions* and *Item 10. Additional Information – Material Contracts* for more information about this transaction.

In March 2012, we also announced a transition to a new Chief Executive Officer. Stephen H. Willard, our Chief Executive Officer since June 2005, resigned as Chief Executive Officer effective March 13, 2012 but remains on our Board of Directors and was an employee of one of our US subsidiaries through December 31, 2012. Michael S. Anderson, the Chief Executive Officer of Éclat, was appointed as Chief Executive Officer of Flamel on March 13, 2012.

In March 2012, we announced the completion of the Phase 1 Study conducted by Merck Serono in connection with the development and license agreement for a long-acting, controlled release subcutaneously-administered formulation of interferon beta-1a using the Medusa platform ("IFN-beta XL").

In June 2012, we announced that our Medusa-formulated interferon alpha-2b (“IFN-alpha XL”) was featured in a lecture and a poster session at the 14th International Symposium on Viral Hepatitis and Liver Disease (ISVHLD) held June 22-25, 2012 in Shanghai, China. The abstracts were entitled "Aggregate report on safety and efficacy of a new sustained release IFN (IFN XL) as compared to standard of care" and "Medusa formulated Interferon-alpha-2b Shows a Favorable Efficacy / Tolerability Profile vs. PEGylated IFN-alpha-2b in Hepatitis C Patients in the Phase 2 Study ANRS HC23 COAT-IFN." The abstracts described a non-inferiority antiviral activity and improved safety profile as compared with ViraferonPeg® (marketed in the U.S. as PegIntron®).

In October 2012, we announced that the U.S. Food and Drug Administration (FDA) has accepted the company's New Drug Application (NDA) for an undisclosed hospital-based product. Flamel has received a Prescription Drug User Fee Act (PDUFA) date, the target date for the FDA to complete its review of the NDA, of May 31, 2013.

In November 2012, we received notice from Merck Serono that it has decided to terminate for convenience its development and license agreement with Flamel for IFN-beta XL. Unfortunately, we believe that while the Medusa platform was progressing, the IFN-beta XL product’s profile and its development timelines no longer met Merck Serono’s commercial needs.

In February 2013, we announced that the Company had completed a $15 million debt financing with Deerfield Management, Flamel’s current largest shareholder. Flamel also announced the appointment of Dr. Gregg Stetsko as Vice President, Research & Development.

Lead Product

The lead product using our Micropump technology is Coreg CR, which we developed with GSK and which is approved, marketed and sold in the U.S. We began work with GSK in 2003 when we entered into a license agreement for use of our Micropump technology for Coreg CR, which is an extended release formulation of carvedilol phosphate. Coreg CR was approved by the FDA in October 2006 and launched in March 2007. We have produced Coreg CR microparticles for GSK on a cost plus basis pursuant to a separate supply agreement that expired on December 31, 2010. In October, 2011, we announced that we signed a new supply agreement with GSK for the production of Coreg CR microparticles and continue to be the sole supplier of Coreg CR microparticles for GSK. Under the agreement, we will receive guaranteed minimum payments to supply Coreg CR microparticles over a minimum period of five years. No earlier than January 1, 2013, GSK may terminate the agreement at their sole discretion by giving six months written notice. The agreement defines the manufacturing relationship between the two companies following the expiration of the previous supply agreement on December 31, 2010. Pursuant to this agreement, we have received a payment of €1.3 million ($1.8 million) during the third quarter of 2011 and a further €1.3 million ($1.8 million) payment in the fourth quarter of 2011, as well as a higher margin on all product produced by Flamel for GSK since January 1, 2011. To date, $23 million in milestone payments have been received from GSK. Flamel still is eligible to receive an additional $2 million if certain milestones are achieved. In 2012, we recognized royalty revenue of $6.9 million.

The Hatch-Waxman exclusivity period for Coreg CR ended on April 20, 2010. It is possible that Coreg CR may experience generic competition from one or more competitors following approval of an Abbreviated New Drug Application (ANDA). To date, four ANDA filings have been submitted to the FDA. The first was submitted by URL Pharma in March 2008 and has not yet received either tentative or final approval. In March 2011, we received notice of a second filing submitted by Lupin Pharmaceuticals, and it has also not received tentative or final approval. In May 2011, we announced the filing of a lawsuit in the U.S. District Court for the District of Columbia against Lupin for infringement of our US Patent No. 6,022,562, which is associated with Coreg CR. In August 2012, the Company concluded a settlement agreement with Lupin and the parties filed a joint stipulation of dismissal on September 11, 2012. We have also received an ANDA letter of notification from Anchen Pharmaceuticals regarding only the 40 mg. dosage strength. In September 2011, Flamel filed a lawsuit in the U.S. District Court for the District of Maryland against Anchen Pharmaceuticals, Inc., for infringement of the same patent. In May 2012, the Company concluded an agreement whereby Anchen agrees to pay the sum of $400,000 in settlement of the claim. In April 2013, we received an ANDA letter of notification from Impax Laboratories. We have submitted a Citizen’s Petition to the FDA that respectfully requests that the FDA require any proposed generic formulations of Coreg CR to meet the same requirements that the FDA required for the approval of Coreg CR, which is a higher standard than is otherwise required under the minimum bioequivalence regulations. In October 2010, the FDA granted our petition in part and denied it in part. To date, no generic formulation of Coreg CR has yet been approved. In addition, US Patent 8,101,209 covering Coreg CR formulation has been granted in the US (Notice of Allowance from the USPTO received on Dec. 12, 2011) and listed in the FDA Orange Book by our partner GSK on February 23, 2012.

Applications Under Development

In October 2012, we announced that the U.S. Food and Drug Administration (FDA) has accepted the company's New Drug Application (NDA) for an undisclosed hospital-based product. Éclat (Flamel's wholly owned subsidiary)has received a Prescription Drug User Fee Act (PDUFA) date, the target date for the FDA to complete its review of the NDA, of May 31, 2013.

Several Medusa-based products have been successfully tested in clinical trials; Medusa's lead internal product candidate IFN-alpha XL (long-acting interferon alpha-2b) is completing a Phase 2 trial in HCV patients (Study "ANRS HC23 COAT-IFN") for which the latest results have been presented at the American Association For The Study Of Liver Diseases (AASLD 2012) held on Nov. 9-13, 2012 in Boston. IFN-alpha XL demonstrated a non-inferiority antiviral activity and improved safety profile as compared with ViraferonPeg® (marketed in the U.S. as PegIntron®).

Acquisition of Éclat Pharmaceuticals

Éclat, a St. Louis, Missouri-based specialty pharmaceutical company, is focused on the development, approval and commercialization of niche brands and generic products. Éclat was established to successfully develop creative and cost-effective ways to deliver pharmaceutical therapy to patients. Whether improving the convenience of drug delivery or improving upon difficult side effect profiles, Éclat's approach is to find solutions to problems with existing therapies. In the shorter term, Éclat has identified several "opportunistic" drug candidates for development. Éclat has initiated the development of a number of them. The company has identified expertise in the regulatory process, the development process and the manufacturing and distribution arenas that it can leverage to bring products to the market.

The acquisition of Éclat was made pursuant to a Membership Interest Purchase Agreement dated March 13, 2012 among Flamel, Flamel US, Éclat Holdings and Éclat. In exchange for all of the issued and outstanding membership interests of Éclat, Flamel US provided consideration primarily consisting of:

- a $12 million senior, secured six-year note that is guaranteed by us and our subsidiaries and secured by the equity interests and assets of Éclat;
- two warrants to purchase a total of 3,300,000 ADSs of Flamel;
- a commitment to make earn out payments of 20% of any gross profit generated by certain Éclat launch products;
- a commitment to make earn out payments of 100% of any gross profit generated by Hycet® up to a maximum of $1 million.

The Purchase Agreement also contains certain representations and warranties, covenants, indemnification and other customary provisions.

Flamel US issued the note pursuant to a Note Agreement among Flamel, Flamel US and Éclat Holdings dated March 13, 2012. The note is payable over six years only if certain contingencies are satisfied, namely that: (a) two or more Éclat launch products are approved by the FDA, or (b) one Éclat launch product is approved by the FDA and has generated $40 million or more in cumulative net sales. We refer to these contingencies as Thresholds. If either Threshold is satisfied, Flamel US will pay 25% of the original principal amount due under the note on each of the third, fourth, fifth and sixth anniversaries of the date of the note. The note accrues interest at an annual rate of 7.5%, payable in kind, until one Éclat launch product is approved by the FDA. After FDA approval of one Éclat launch product is obtained, any interest previously capitalized is payable in cash no later than nine months following FDA approval, and any future interest is payable in cash when due. The Note Agreement also contains certain covenants, events of default and rights in the event of a change of control of Flamel that are described in more detail in *Item 10. Additional Information – Material Contracts*.

In addition to the Note, we also issued to Éclat Holdings two six-year warrants to purchase an aggregate of 3,300,000 ADSs, each representing one ordinary share, of Flamel. One warrant is exercisable for 2,200,000 ADSs at an exercise price of $7.44 per ADS, and the other warrant is exercisable for 1,100,000 ADSs at an exercise price of $11.00 per ADS. The warrants were approved by the holders of Flamel's ordinary shares in June 2012. See *Item 10. Additional Information – Material Contracts* for more information on the warrants. In connection with the issuance of the warrants, Flamel also entered into a registration rights agreement with Éclat Holdings, pursuant to which Flamel filed a registration statement with the SEC covering the resale of the ADSs issuable upon exercise of the Warrants in September 2012.

Corporate Information

The Company was incorporated as a *Société Anonyme (or SA)*, a form of corporation under the laws of the Republic of France, in August 1990 as Flamel Technologies S.A. and its shares, represented by American Depositary Shares, began to be quoted on the NASDAQ National Market in 1996 and are now quoted on the NASDAQ Global Market. The life of the company expires in 2099, unless extended. Flamel's principal place of business is located at Parc Club du Moulin à Vent, 33, avenue du Docteur Georges Lévy, 69693 Venissieux Cedex, France, telephone number +33 472 78 34 34.

The Company has two direct wholly owned subsidiaries: Flamel US Holdings, Inc., a Delaware corporation, created for the acquisition of Éclat Pharmaceuticals in March 2012, and Flamel Technologies, Inc., a Virginia corporation. Éclat Pharmaceuticals, LLC, a Delaware limited liability company, is a wholly owned subsidiary of Flamel US Holdings, Inc. Talec Pharma, LLC, a Delaware limited liability company, is a wholly owned subsidiary of Éclat Pharmaceuticals, LLC. A complete list of the Company's subsidiaries can be found in Exhibit 8.1.

Market Opportunities

Flamel has developed and owns outstanding drug delivery platforms that are able to tackle key challenges in the formulation of drugs:

- For injectable formulations, Medusa® (and its application DeliVax®); and,

- For oral formulations, Micropump® (and its applications LiquiTime® and Trigger-Lock™).

Drug delivery platforms are of particular interest for managing the life cycle of medicines, as they offer many advantages: i.e., improvement of drug characteristics such as bioavailability, pharmacokinetics, efficacy, compliance, and side effects; protection of market position through patent extension or differentiation; and extension of market to new indications thanks to improvement of the drug's characteristics. The drug delivery industry landscape has dramatically changed over the past decade and even more so during the past five years, largely as a function of the growing importance of generic drugs. Generics - especially in the small molecule space - have accelerated the demand for drug delivery solutions while, at the same time, reducing the overall market for drug-delivery formulations due to reduced pricing power.

This dynamic is beginning to play itself out in the large molecule space as well. In addition, the overall landscape of the Pharma/Biotech industry has changed, as consolidation has reduced our pool of potential partners and further accelerated the competition among drug delivery companies. Over the past ten years, numerous drug delivery companies have been acquired (partly or entirely) by biopharmaceutical, generic or other drug delivery companies. By acquiring drug delivery platforms, pharmaceutical companies are internalizing their previously outsourced R&D efforts while potentially preventing competitors from accessing these technologies. In the meantime, certain drug delivery companies have consolidated their existing positioning or have entered new markets via M&A transactions and/or restructuring. Very few of Flamel's "historical" competitors, such as Octoplus, still pursue a pure Drug Delivery business model as many other have moved or are moving to the specialty pharma model (e.g. Alkermes, BioAlliance, Depomed, Ethypharm, Eurand, Life Cycle Pharma) or to the fully integrated biotech model (e.g. Human Genome Sciences, developing biotherapeutics fused human serum albumin, acquired by GlaxoSmithKline in July 2012, Nektar Therapeutics developing PEGylation technology which is used e.g. in UCB's Cimzia® approved by the FDA for Crohn's disease).

The global drug delivery market was estimated by BCC Research to reach $145 billion by the end of 2012. However, the industry faces many challenges. There are four main forces currently affecting all standalone drug delivery companies and forcing the industry to adapt and to change:

- The rise of generics
  - Ø Customers need to fill their drug pipelines with patent-protected reformulations to attenuate generics impact (Life Cycle Management)
- The rise in costs for new product development
  - Ø Increasing development costs for New Chemicals Entities and New Biological Entities (NCEs and NBEs) is in favor of developing new formulations of already approved drugs at lower costs
- Commoditization and acquisition of drug delivery technologies
  - Ø More and more drug delivery customers (mainly “Big Pharmas”) have developed internal drug delivery capabilities
  - Ø Integration of the drug delivery-based formulation development at much earlier stage in the overall pharmaceutical development
- Higher regulatory and reimbursement hurdles.
  - Ø “As good as” with increased convenience is now insufficient to get approved and reimbursed for drug products; therefore, technology-based drugs need to show improved efficacy too.

These forces have affected the small molecule space to a greater extent, as biologics enjoy higher barriers to entry and have been sheltered as a consequence. But they are at work in the biologics space as well. In particular, in today’s environment, a drug has to demonstrate significant therapeutic efficacy advantage over current standard of care in order to successfully solicit third party payer coverage. It has a serious impact on drug delivery companies as they have to now demonstrate, through costly phase 3 trials, therapeutic efficacy of their new formulations. Interestingly, this trend directly contradicts the “improvement in patients’ convenience first” approach supported in the past by drug delivery companies. More positively, in parallel, the FDA has encouraged drug companies developing enhanced formulations to use an abbreviated regulatory pathway: the 505(b)2 NDA. Most drug delivery companies today are using this approach or the supplemental NDA pathway (sNDA). A sNDA is necessary to market an already approved drug for a new indication, or in a different dosage form or formulation. However, this approach requires cross-referencing to the originator’s drug dossier, and consequently, an alliance with the originator’s company.

Because the drug delivery industry is highly competitive participants must find ways to lessen the pressure and increase profitability. The “new” Flamel, resulting from the combination of its existing proprietary drug delivery platforms with the established commercial capability of Éclat, is evolving into a Specialty Pharma company focusing on re-formulations and requiring shorter product development cycles by using a “fast track” NDA process (505(b)2). The pharmaceutical sector, with an impending “patent cliff“, is forcing Big Pharma to reorganize and creating niche opportunities for Specialty Pharma companies like the “new” Flamel.

Business Strengths and Strategies

Our core strength is as a science-based, market-focused innovator of drug delivery platforms and products. The key elements of our strategy that enable us to build upon our strengths are:

- to maximize the potential of our existing drug delivery platforms;
- to develop additional drug delivery platforms;
- to develop proprietary and new formulations of compounds; and,
- to leverage capabilities of our drug delivery platforms with pharmaceutical partners.

We believe that our **Medusa**-based formulations give us a competitive advantage in developing peptides, proteins, as well as other large biological and small chemical drugs (see Section "Medusa Delivery Platform for the delivery of Therapeutic Proteins, Peptides and Small Molecules" below). Medusa-based formulations permit drugs' full activity to be preserved and, extended release, as well as other advantages such as greater solubility, stability, and resistance to aggregation. Overall, Medusa improves dosing or the route of administration (e.g. switching from intravenous to subcutaneous injection), compliance (e.g. from once-a-day to once-a-week) and side-effects profile, while potentially improving efficacy. . We will continue to partner our proprietary formulation capabilities with pharmaceutical companies and biotechnology partners and seek to commercialize and/or partner internally developed products after proof of concept is achieved.

In addition, we also believe in the competitive advantages represented by the versatility of **Micropump**, (see Section "Micropump: Delivery Platform for the Oral Administration of Drugs" below) which permits us to develop differentiated product profiles under various dosage forms (e.g. capsules, tablets, sachets or oral stable liquid controlled release suspensions (**LiquiTime**®)). With **Trigger Lock**™ successfully addressing the issue of narcotic/opioid analgesics tampering, we have broad and versatile presentations to serve all markets from pediatric to geriatric.

Altogether, our innovative drug delivery platforms allow us to select unique product development opportunities, from the Life Cycle Management (LCM) of marketed products, including Biobetters, (established market and proven clinical development approaches as starting points via 505(b) 2 or ANDA regulatory paths), to the development of new compounds, biological or chemical (via NDA regulatory path). Competitive differentiated product profiles (e.g. improvement of efficacy and/or bioavailability and/or pharmacokinetics) are being developed by including our innovative drug delivery platforms in their formulations. Those product development opportunities offer the ability to grow market share and also protection of market position through patent extension and/or product differentiation (incl. new indications and new patient populations) in multiple marketplaces. Indeed, as part of our new business model, and the building-up of an internal products portfolio, several products formulated using either Micropump or LiquiTime or Medusa are under development at Flamel; other Trigger-Lock based products are under consideration. Those products will be marketed either by the Company and/or by partners via licensing/distribution agreements.

Under our partnership agreements, our partners typically assume responsibility for all formulation development, manufacturing, polymer supply, clinical, regulatory and marketing costs and make payments to us at the time the agreement is signed and upon the achievement of significant technical, clinical and regulatory milestones. We also typically are entitled to receive ongoing royalty payments on the sales of pharmaceuticals that incorporate our drug delivery platforms.

The acquisition of Éclat provides the Company with additional competencies and business strengths. To complement the science oriented strengths of Flamel, we now have enhanced our ability to pursue commercial opportunities and identify new product candidates and have gained a product portfolio of one FDA approved product that is currently marketed in the U.S. (Hycet®) as well as a portfolio of other products in various stages of development. We anticipate that in some instances, this enhanced commercialization capability will allow us to retain a greater portion of the economic benefits associated with sales of products using our technologies. We also benefit by the addition of a different perspective on the business and products to be developed in the future.

On October 18, 2012, Flamel received FDA's acceptance for its first NDA with a PDUFA date of May 31, 2013. For competitive reasons, the Company has decided not to identify the product at this time, but intends to provide additional information at a later date. Flamel believes that the product could have a significant impact on the company's revenue generation and favorably impact its progression to profitability. If approved by the FDA, the product is expected to generate approximately $25 million to $35 million or more in peak annual revenues, subject to the Company being able to market and price the product successfully, of which there can be no assurance. This NDA acceptance is an important milestone for our business and we believe it demonstrates the expanded capabilities of Flamel. This is the first of what we expect to be multiple new product applications to come from our internal pipeline over the next few years.

Medusa Delivery Platform for the delivery of Therapeutic Proteins, Peptides and Small Molecules

The Medusa drug delivery platform consists of proprietary hydrogels for the formulation and/or the extended release of a broad range of biologics (including proteins, antibodies, peptides and vaccines) and of small molecules (injectable drugs). The hydrogels, which are easy and cost effective to produce under EMA/FDA cGMP requirements, have been proven to be safe and biodegradable. A comprehensive ADME and regulatory toxicology package has been completed; a type IV Drug Master File (DMF) has been filed with the US FDA (assigned number 024634) in February 2011 and recently updated in February 2013. Medusa enables the controlled delivery from 1 day up to 14 days of non-denatured or non-modified drugs that remain fully active (as distinguished from protein engineering or chemical modification approaches). It is used to develop biobetters with potentially improved efficacy and reduced toxicity, as well as greater patient convenience. In addition, DeliVax®, Medusa's vaccine applications, permits the efficient formulation of vaccines or combinations of vaccines.

Flamel's Medusa, a non-modifying hydrogel depot formulation approach, is a versatile drug carrier for the development of novel and second-generation long-acting native biologics (proteins and peptides), as well as small molecules. Medusa polymer is made of glutamic acid, a naturally occurring aminoacid, and Vitamin E. The polymer is amphiphilic and spontaneously forms stable hydrogel in water. The hydrogel consists of hydrophobic nanodomains rich in Vitamin E and hydrophilic polyglutamate that are exposed to water. They are robust over a wide range of pH values and can be stored as either a stable liquid or a stable dry form that can be easily reconstituted in water for injection. The design of the Medusa "polypeptide-like" aminoacid polymers allows non-covalent/non-modifying capture and subsequent delivery of native peptide or protein drugs. Once injected into the body, the hydrogel releases the captured-drugs in a controlled manner and over an extended period of time. Both processes (capture and release) are non-denaturing, which preserves structural integrity - and hence the biological activity - of the drug. The transient, non-covalent interactions dictate the pharmacokinetic profile (Cmax and AUC in particular) of the released drugs.

- The biological activity is maintained: no modification of the biotherapeutic which is only adsorbed on Medusa's hydrogel via electrostatic bonds. There are no chemical bonds compared to protein engineering drug delivery approaches (such as PEGylation, protein fusion, etc.) which often lead to immunogenicity. With Medusa, because the formulation is non-denaturating, the active drug is delivered in its native form which can potentially reduce the side effects relative to competing approaches;

- The safety profile versus the original biologic is improved, the result of a lower Cmax and a more regular concentration profile;

- Medusa's hydrogel is made of safe and fully biodegradable and biocompatible "polypeptide-like" amino-acid polymers which are non-immunogenic and non-toxic, with no local irritation nor allergic reactions, as proven in human clinical trials. Comprehensive ADME and regulatory toxicology package completed (included in the DMF);

- Medusa has the ability to solubilize and stabilize insoluble and/or unstable proteins/peptides and prevent their aggregation. Today companies are addressing stabilization issues earlier in the development process;

- The polymerization process is simple; it is easy to manufacture under cGMP requirements, to store and to scale up (from current 50L scale to commercial scale of 250L);

- It's a "Protein friendly" process based on fully aqueous solution (solvent- and surfactant-free): compatible with sensitive/fragile molecules, suitable for both hydrophobic and hydrophilic biotherapeutics;

- Also applicable to small molecules, Medusa can be useful to improve the compliance (e.g. Tigecycline); and,

- Strong intellectual property position (over 50 patent families).

The Medusa drug delivery platform is patented under Flamel Technologies' key patent WO 2000/30618, already granted in the United States and in Europe, and recently granted in Japan. It is being utilized in collaborations with leading pharmaceutical and biotechnology companies.

According to BCC Research, a market research company, global sales of biologics were approximately $180 billion in 2012, and are expected to reach $239 billion by 2015, which represents a compound annual growth rate (CAGR) of 9.9%.

Lead Product Under Development Based on the Medusa Technology

Interferon Alpha

Medusa's lead internal product candidate IFN-alpha XL (long-acting interferon alpha-2b) is completing a Phase 2 trial in HCV patients (Study "ANRS HC23 COAT-IFN") for which the latest results have been presented at the American Association For The Study Of Liver Diseases (AASLD 2012) held on Nov. 9-13, 2012 in Boston. IFN-alpha XL demonstrated a non-inferiority antiviral activity and improved safety profile as compared with ViraferonPeg® (marketed in the U.S. as PegIntron®).

We believe that the Medusa delivery platform has the potential to improve formulations of many important biological drugs. Our formulation of interferon alpha (IFN-alpha XL) is one of our more important development programs and is an example of the potential of the Medusa platform to improve the safety and efficacy of therapeutic proteins. Interferon-alpha is a naturally occurring protein that the body uses as part of its immune response and which is part of the current standard of care for the treatment of Hepatitis C virus.

In December 2009 the *Agence Nationale de Recherche sur le SIDA et les Hépatites Virales* (*ANRS*) initiated a twelve week Phase 2 study comparing two dosage forms of our IFN-alpha XL plus ribavirin versus PegIntron® plus ribavirin in genotype 1 hepatitis C patients. The intermediate analysis of the Phase 2 study of our long-acting interferon alpha-2b (IFN-α XL was presented in November 2011 at the AASLD annual meeting in San Francisco. A reduction in side effects of at least 30% compared to Standard of Care, i.e., PEGylated IFN-alpha and weight-based ribavirin combined therapy, was observed. An abstract describing the interim efficacy results has been accepted for presentation at the 14th International Symposium on Viral Hepatitis and Liver Disease (ISVHLD) meeting that will be held in June 2012 in Shanghai. The upcoming data presentation suggests that the antiviral activity of IFN-α XL is at least similar to that of reference PEGIFN-α 2b in this 3-month course of combined therapy, which would confirm the non-inferiority objective.

We have conducted two previous studies that demonstrated promising results of the formulation as compared to Intron-A® (immediate release interferon-alpha 2b, marketed by Schering Plough, since acquired by Merck & Co., Inc.) and PegIntron (pegylated interferon-alpha 2b, also marketed by Schering Plough (since acquired by Merck& Co., Inc.).

Our first study compared Interferon-alpha XL with Intron-A. The dose-escalating study was conducted in 53 subjects with chronic hepatitis C. Thirty-nine participants were assigned to receive a single subcutaneous injection of one of three escalating doses of IFN-alpha XL (12 - 14 patients per dose). The three IFN-alpha XL groups received an injection of 9 million international units (MIU), 18 MIU, and 27 MIU, respectively. A cohort of 14 patients received three subcutaneous injections of a standard dose of Intron-A (3 MIU) over one week as a comparator. All patients completed the study, and no serious adverse events were reported.

Adverse events were similar to what has been reported in other studies of interferon therapy and were transient in duration and mild to moderate in severity. Patients receiving IFN-alpha XL experienced fewer adverse events than patients receiving Intron A, even when the weekly dosage of IFN-alpha XL was at its highest level. Pharmacokinetic data demonstrate that the Medusa formulation provides sustained release of IFN-alpha XL over one week.

The second trial we completed compared our Interferon-alpha XL with PegIntron. The full data set was presented at the Annual Meeting for the European Association for the Study of the Liver in Milan in April, 2008. Results showed a statistically significant reduction in viral load after two weeks in the group comprising genotype-1 naïve patients, and non-responder/relapsed patients to pegylated interferon plus ribavirin. Importantly, these patients also benefitted with respect to tolerance of the treatment, as reported adverse events were fewer in those patients administered Interferon-alpha XL than in those patients administered PegIntron.

In June 2012, we announced that our IFN-alpha XL was featured in a lecture and an oral poster session at the 14th International Symposium on Viral Hepatitis and Liver Disease (ISVHLD) held June 22-25, 2012 in Shanghai, China. The abstracts were entitled "Aggregate report on safety and efficacy of a new sustained release IFN (IFN XL) as compared to standard of care" and "Medusa formulated Interferon-alpha-2b Shows a Favorable Efficacy / Tolerability Profile vs. PEGylated IFN-alpha-2b in Hepatitis C Patients in the Phase 2 Study ANRS HC23 COAT-IFN."

The worldwide market for interferon alpha drugs exceeded $2.4 billion in 2012. We continue to explore licensing opportunities with interested parties for the further development of the Medusa platform with respect to interferon-alpha.

Other Products Under Development Based on the Medusa Drug Delivery Platform

Several Medusa-based products have been successfully tested in clinical trials. In November 2012, we received notice from Merck Serono that it has decided to terminate for convenience its development and license agreement with Flamel for IFN-beta XL. Unfortunately, we believe that while the Medusa platform was progressing, the IFN-beta XL product's profile and its development timelines no longer met Merck Serono's commercial needs.

We have feasibility study relationships with pharmaceutical and biotechnology partners. These projects involve both novel and already-marketed molecules. Flamel expects some of these projects to evolve into license agreements as a function of many factors. These include the promise of the molecule itself (particularly with respect to novel molecules there is a high rate of attrition); the success of formulation work that we conduct for our partners; the evolving strategy and marketing focus of our partners; and the pharmaco-economics associated with the eventual product and the indication(s) for which it is being developed.

Focus on Medusa-based "biobetters" development: Biobetter drugs obtained through protein engineering or chemical modification become New Biological Entities (NBEs) leading to as many clinical and toxicity studies than the original molecule, and consequently, losing the key advantages of biosimilars. Medusa-based biobetter drugs are improved versions of original biologics / biosimilars which do not modify or denature the original drug and therefore, can benefit from shorter and cost effective (lower cost and ease of scale-up) development and regulatory pathways, very similar to biosimilars. The Biobetter opportunity can be summarized as follows:

- Validated drugs, established market and proven clinical development approaches as starting points
- Product differentiation e.g. improvement of efficacy and/or bioavailability and/or pharmacokinetics
- Protection of market position through patent extension and/or product differentiation
- Extension of market to new indications and new patient populations via product differentiation
- Ability to grow market share and resist price competition

Even if there is no abbreviated regulatory route for biobetters,the 505(b)2 pathway is considered to be the appropriate regulatory pathway. The expected risk of failure is lower than for most new drugs as it is a second generation of a drug that has already been a commercial success. The risk is lowered using Medusa drug delivery platform (no modification of the active) compared to other approaches, such as protein engineering or chemical modifications.

Another area that is of particular interest to the Company, is the development of subcutaneously administered formulations of small molecule drugs that are otherwise given intravenously. Due to the heightened solubility that the Medusa platform enables for otherwise poorly-soluble drugs, we are able to create formulations that may be administered subcutaneously, which creates "pharmacoeconomic" and convenience benefits for caregivers and patients. We anticipate that this facet of the Medusa platform will generate increased interest over the coming year.

In addition, as part of our new business model, and the building-up of an internal products portfolio, one particular Medusa-based product is under development at Flamel; several others are under consideration. Those products will be marketed either by the Company and/or by partners via licensing/distribution agreements.

Micropump: Delivery Platform for the Oral Administration of Drugs

The Micropump controlled-release drug delivery platform (**oral drugs**) is designed to increase the absorption time of drugs, particularly for drugs only absorbed in the small intestine. Micropump enables the achievement of precise pharmacokinetics. Micropump can be presented in various dosage forms such as capsules, tablets, sachets or oral suspensions (**LiquiTime**®) without modifying the release rate. Flamel has also developed another drug delivery platform for oral drugs, i.e. **Trigger Lock**™ for the controlled release of narcotic and opioid analgesics while defeating most commonly employed methods of tampering. This technology has successfully transitioned to commercial stage with Coreg CR®, a Micropump-based controlled-release formulation of carvedilol phosphate, sold in the US since 2007 by GlaxoSmithKline (GSK).

Flamel's Micropump is a controlled-release platform which permits either extended, or both delayed and extended, delivery of small molecule drugs. It is particularly suitable for drugs with a narrow window of absorption in the upper part of the small intestine.

Micropump technology consists of a multiple-dose system containing 5,000 to 10,000 microparticles per capsule or tablet. The 200-500 microns diameter-sized microparticles are released in the stomach and pass into the small intestine, where each microparticle, operating as a miniature delivery platform, releases the drug by osmotic pressure at an adjustable rate and over an extended period of time.

The design of the Micropump microparticles allows an extended transit time in the small intestine with a mean plasma residence time extended up to 24 hours (Micropump I), which is especially suitable for short-lived drugs known to be absorbed only in the small intestine. The microparticles' design can be adapted to each drug's specific characteristics by modifying the coating thickness and composition (including GRAS excipients encapsulated with the drug) for improved efficacy (i.e., extending therapeutic coverage), reduced toxicity and/or side effects (i.e., reduced Cmax or peak drug concentration in the plasma) and improved patient compliance (once-a-day regimen). Micropump allows developing extremely precise pharmacokinetic profiles [extended (and/or delayed) release (Micropump II)] of single or combination of drugs, in a variety of formats (pill, tablet, capsule, sachet, or liquid).

In addition, Micropump allows:

- Extended release liquid formulations, due to the size of the microparticles, of drugs for patients having issues swallowing tablets or capsules such as children and the elderly (**LiquiTime**); and,
- Tamper-resistant controlled release formulations of narcotics and other drugs susceptible to abuse (**Trigger Lock**).

Micropump has a variety of competitive strengths:

- One highly successful product is already on the market using this technology;
- Micropump permits the extended delivery of drugs with a narrow window of absorption, i.e., Micropump I (up to 24 hours) or, both delayed and extended delivery of these drugs, i.e., Micropump II (up to 12 hours following the drug uptake and for a release over an additional 12 hours);
- It allows the controlled-release of poorly soluble (< 0.01mg/L) as well as highly soluble (> 500g/L) drugs;
- It allows combination of different drugs whose release can be controlled separately;
- It is applicable to low dose (4 mg) or high dose (1,000 mg) drugs;
- Versatile presentation to serve all markets from pediatric to geriatric: Suspensions (easy to swallow (LiquiTime), Capsules, Tablets and Sachets;
- Proof of concept work for a controlled release liquid suspension has been done and tested in humans (pediatrics; LiquiTime);
- Taste masking properties;
- It reduces intra- and inter-patient variability;

- Trigger Lock, a special application based on Micropump, is developed for the controlled release of drugs prone to abuse (tamper resistant, avoids dose dumping);

- The formulation process is easy to scale up to industrial high-volume production (based on fluidized bed spray coating and granulation) and is cost effective;

- Flamel owns a cGMP FDA-approved manufacturing site (Pessac, France); and,

- Strong intellectual property position (over 40 patents).

The Micropump drug delivery platform is patented under Flamel Technologies' key patent WO 96/11675, granted in the United States, Europe and Japan; US Patent 8,101,209 covering Coreg CR formulation has been granted in the US and listed at the FDA Orange Book by our partner GSK. The Micropump drug delivery platform is being utilized in collaborations with leading pharmaceutical and biotechnology companies.

Trigger Lock™

Opioid analgesics are used to treat patients suffering from severe and chronic pain. The market for opioid drugs in the seven major markets (USA, Japan, and 5 European countries) was estimated to exceed $7.4 billion in 2010, dominated by oxycodone. It is forecasted to reach $7.9 billion by 2012.

A major problem faced by the industry is the growing abuse and misuse of opioids by drug abusers, who extract the opioids from the drugs and achieve their immediate release. The proportion of narcotic/opioid analgesics abuse associated with emergency room admissions has more than tripled, from 6.8% in 1998 to 26.5% in 2008 (TEDS report, July 15, 2010). Narcotic/opioid analgesics abuse continues to increase as current products remain easy to abuse.

Trigger Lock successfully addresses the issue of narcotic/opioid analgesics tampering:

- Micropump particles cannot be crushed to extract the narcotic/opioid analgesics;
- Prevent misuse of scheduled drugs such as narcotic/opioid analgesics;
- Additional modifications tailored to prevent other less publicized methods of foiling controlled release systems;
- Provides either bioequivalent or improved pharmacokinetics to marketed narcotic/opioid analgesics; and,
- May be applied to novel, already-marketed, or off-patent narcotic/opioids.

A Trigger Lock application is in co-development with a major pain therapy company. On April 28, 2011, Flamel Technologies announced a license agreement with a leading specialty pharmaceutical company for the development and commercialization of two molecules for pain indications. Flamel has received an upfront license fee of $3 million, and may also be entitled to milestones, and mid-single digit royalties upon eventual sale of the respective products.

The FDA's move to restrict prescribing extended-release opioid analgesics should benefit tamper-resistant formulations such as Trigger Lock-based formulations of opioids. US FDA has issued Draft Guidance for Abuse Deterrent opioids on January 9, 2013. Trigger Lock satisfies:

- Laboratory-based in vitro manipulation and extraction studies (Category 1) – Success with Trigger Lock
- Pharmacokinetic studies (Category 2) – Success with Trigger Lock
- Clinical abuse potential studies (Category 3) – To be performed
- Analysis of post-marketing data to assess the impact of an abuse-deterrent formulation on actual abuse in a community setting (Category 4) – Post-Marketing

On April 16, 2013, FDA approved abuse-deterrent labeling for reformulated OxyContin (oxycodone hydrochloride controlled-release tablets from Purdue Pharma L.P.). Additionally, because original OxyContin provides the same therapeutic benefits as reformulated OxyContin, but poses an increased potential for certain types of abuse, the FDA has determined that the benefits of original OxyContin no longer outweigh its risks and that original OxyContin was withdrawn from sale for reasons of safety or effectiveness. Consequently, the FDA will not accept or approve ANDAs for generic versions of OxyContin that lack abuse-deterrent properties.

LiquiTime®

LiquiTime allows the development of oral controlled release liquid formulations of drugs for patients who have difficulty swallowing tablets or capsules, such as children and the elderly. LiquiTime has reached clinical proof of concept in humans for a liquid suspension of an undisclosed drug for treatment of children (confidential). Flamel Technologies has several programs at various stages on undisclosed molecules.

LiquiTime successfully addresses the stability of sustained release liquid formulations:

- Easy to swallow, good mouth feeling, taste masked
- Applicable to a wide range of drugs, not limited to ionic drugs as with resin-complex based technology
- Zero-order kinetics
- Possibility to combine in the same formulation of either immediate release and extended release kinetics for the same drugs or different drugs with different release kinetics
- Uses “Generally Regarded as Safe” (GRAS) materials to assure safety
- Ease of scale-up to commercial quantities
- Clinical proof of concept achieved in humans; and,
- Broad and strong intellectual property protection (several patents granted e.g. in the US, EU and Japan)

Products Based on the Micropump, Trigger Lock and LiquiTime Platforms

Coreg CR

The lead product using our Micropump technology is Coreg CR, which we developed with GSK and which is approved, marketed and sold in the U.S. Coreg CR is an extended-release formulation of Coreg (carvedilol phosphate), a beta blocker that is considered the standard of care for the treatment of moderate to severe heart failure and left ventricular dysfunction following myocardial infarction. Coreg CR was approved by the FDA on October 20, 2006 for use in the treatment of moderate to severe congestive heart failure; left ventricular dysfunction following myocardial infarction; and hypertension. We began work with GSK in 2003 when we entered into a license agreement for use of our Micropump technology for an extended release formulation of carvedilol phosphate; the product was launched in March 2007. Prior to 2011, we produced Coreg CR microparticles on a cost plus basis pursuant to a separate supply agreement that expired on December 31, 2010. From January 1, 2011 until October, 2011 we supplied Coreg CR microparticles to GSK as a unilateral accommodation so as to secure their supply while we negotiated a new supply agreement. In October, 2011, we announced that we signed a new supply agreement with GSK for the production of Coreg CR microparticles and we remain the sole supplier of Coreg CR microparticles for GSK. Under the agreement, we will receive guaranteed minimum payments to supply Coreg CR microparticles over a minimum period of five years. No earlier than January 1, 2013, GSK may terminate the agreement at their sole discretion by giving six months written notice. The agreement defines the manufacturing relationship between the two companies following the expiration of the previous supply agreement on December 31, 2010. Pursuant to the agreement, we received a payment of €1.3 million ($1.8 million) during the third quarter of 2011 and a further €1.3 million ($1.8 million) payment in the fourth quarter of 2011, as well as a higher margin on all product produced by Flamel since January 1, 2011. To date, $23 million in milestone payments have been received from GSK and Flamel is eligible to receive an additional $2 million if certain milestones are achieved. In 2012, we recognized royalty revenue of $6.9 million.

The Hatch-Waxman exclusivity period for Coreg CR ended on April 20, 2010. It is possible that Coreg CR may experience generic competition from one or more competitors following approval of an Abbreviated New Drug Application (ANDA). To date, four ANDA filings have been submitted to the FDA. The first was submitted by URL Pharma in March 2008 and has not yet received either tentative or final approval. In March 2011, we received notice of a second filing submitted by Lupin Pharmaceuticals, and it has also not received tentative or final approval. In May 2011, we announced the filing of a lawsuit in the U.S. District Court for the District of Columbia against Lupin for infringement of our US Patent No. 6,022,562, which is associated with Coreg CR. In August 2012, the Company concluded a settlement agreement with Lupin and the parties filed a joint stipulation of dismissal on September 11, 2012. We have also received an ANDA letter of notification from Anchen Pharmaceuticals regarding only the 40 mg. dosage strength. In September 2011, Flamel filed a lawsuit in the U.S. District Court for the District of Maryland against Anchen Pharmaceuticals, Inc., for infringement of the same patent. In May 2012, the Company concluded an agreement whereby Anchen agreed to pay the sum of $400,000 in settlement of the claim. In April 2013, an ANDA letter of notification from Impax Laboratories has been received. We have submitted a Citizen's Petition to the FDA that respectfully requests that the FDA require any proposed generic formulations of Coreg CR to meet the same requirements that the FDA required for the approval of Coreg CR, which is a higher standard than is otherwise required under the minimum bioequivalence regulations. In October 2010, the FDA granted our petition in part and denied it in part. To date, no generic formulation of Coreg CR has yet been approved. In addition, US Patent 8,101,209 covering Coreg CR formulation has been granted in the US (Notice of Allowance from the USPTO received on Dec. 12, 2011) and listed in the FDA Orange Book by our partner GSK on February 23, 2012.

Coreg and Coreg CR are the only beta blockers indicated for the severe form of heart failure. Coreg initially attained this leadership position despite the fact that it was not available in a once-daily formulation, unlike many others of the beta blocker class.

Earlier generations of beta blockers were not widely used in the treatment of hypertension because of perceived drawbacks. Perhaps the greatest of these drawbacks was the fact that many other beta blockers have been associated with increased glycemia levels in Type II diabetic patients. By contrast, Coreg has been proven clinically not to cause increased glycemia levels in diabetic patients, of which there are over thirteen million Type II diabetic hypertensives in the United States. Type II diabetics who suffer from hypertension are defined by the American Diabetes Association as suffering from complicated hypertension, meaning that they are recommended to reduce their blood pressure to a level of 130/80 (as opposed to 140/90 for essential hypertension).

Carvedilol is a non-selective antagonist of Beta 1, Beta 2 adrenergic receptors and a selective antagonist of Alpha 1 adrenergic receptors. It has been demonstrated to have notable anti-inflammatory properties, in distinction to most other beta blockers. Research further suggests that carvedilol possesses significant anti-oxidative effects, which are beneficial to vascular health.

Other Products Under Development Based on Micropump, Trigger Lock and LiquiTime Platforms

We have licensed our Micropump formulation of controlled release aspirin to New Haven Pharmaceuticals. Further, we have licensed the Micropump platform for the development of a controlled release formulation of a central nervous system medication. The formulation development work that we are engaged in is intended to result in a product with further enhanced controlled release characteristics From time to time we have conducted Micropump/LiquiTime feasibility studies on other proprietary therapeutic compounds under confidentiality agreements with the pharmaceutical companies owning the rights to these compounds. Such contracts provide us with the possibility for expanded relationships. Moreover, these relationships are invaluable insofar as our potential partners often are able to identify opportunities for the Micropump platform from their internal pipeline, opportunities which we would not otherwise know.

We are working with a specialty pharmaceutical company to develop formulations using our Micropump/Trigger Lock platform. We announced in April 2011 that we had entered into a license and development agreement for the development and commercialization of two molecules for pain indications that are AB rated formulations of products that are already marketed in the United States. These are Schedule II listed drugs and the formulations would enjoy the potential advantages of Trigger Lock with respect to our ability to create an abuse-resistant product. We now are working on three separate molecules to be formulated using our Trigger Lock platform.

In addition, as part of our new business model, and the building-up of an internal products portfolio, several products formulated using either Micropump or LiquiTime are under development at Flamel; other Trigger-Lock based products are under consideration. Those products will be marketed either by the Company and/or by partners via licensing/distribution agreements.

Éclat Products

Éclat, acquired in March 2012, has one FDA-approved product on the market in the U.S. - Hycet®, (hydrocodone bitartrate and acetaminophen oral solution) and its generic equivalent. Hycet® is indicated for the relief of moderate to severe pain in patients age two or older. It contains the most commonly prescribed dose of hydrocodone bitartrate (7.5 mg/15 mL) in combination liquid form and has an acetaminophen concentration (325 mg/15 mL) that is lower than many competing products. The FDA has declared that by January 14, 2014, prescription products containing over 325mg of acetaminophen should be removed from the market, and the agency intends to take action to withdraw product approvals if companies do not voluntarily comply. We believe this will require the vast majority of prescription acetaminophen products currently on the market to either withdraw or reformulate, and reformulation will require submission of a new marketing application. Net revenues in 2012 for Hycet and its generic equivalent amounted to $0.8 million, and the total generic market for the product is estimated to grow to approximately $15 million.

Éclat also has a portfolio of other potential products in various stages of development. On October 18, 2012, Flamel received FDA's acceptance for its first NDA with a PDUFA date of May 31, 2013. For competitive reasons, the Company has decided not to identify the product at this time, but intends to provide additional information at a later date. Flamel believes that the product could have a significant impact on the company's revenue generation and favorably impact its progression to profitability. If approved by the FDA, the product is expected to generate approximately $25 million to $35 million or more in peak annual revenues, subject to the Company being able to market and price the product successfully, of which there can be no assurance. This NDA acceptance is an important milestone for our business and we believe it demonstrates the expanded capabilities of Flamel. This is the first of what we expect to be multiple new product applications to come from our internal pipeline over the next few years.

Strategic Alliances

In order to develop and apply our drug delivery platforms efficiently and to effectively commercialize products, we have entered into, and intend to continue to enter into, various types of collaborative arrangements with biotechnology and pharmaceutical company partners. Such arrangements typically provide funding for development work and access to target compounds and related know-how and, in many cases ultimately, provide distribution capabilities for any resulting products either directly or by providing for the option to enter into future license agreements.

Developing alliances was the only strategy for Flamel's previous business model:

- Collaboration and license agreements generate cash to support Company's internal development programs - approximately $132 million from 2005 to 2012;
- During the 2005-2012 period, Coreg CR royalties amounted to $49 million. Production of Coreg CR microparticles was $78 million gross;
- The funding of R&D tax credits by the French Government from 2005 until 2012 has totaled $42 million, which accounts for about 15.2% of Flamel's total R&D expenditure in France during the same period.
- Flamel has successfully applied for various grants; in 2012 Flamel has been granted a non-interest-bearing loan of 0.8$ million and grant of $0.5 million to assist financing of the projects under development with Digna Biotech. In addition, the French National Agency for Research on AIDS and Viral Hepatitis covers around 30%, i.e. $0.6 million, of the total costs of the current IFN-alpha XL phase 2 clinical study.

Those partnerships provided entry to new product development opportunities and access to complementary expertise (medical and commercial), e.g.:

- FDA-approved Coreg CR (carvedilol phosphate) sold by GSK in the US

However, those business activities with Pharma and Biotech companies strongly depend on partners' corporate strategic priorities. In early 2012, we discontinued our Medusa platform collaboration with Pfizer following their decision not to pursue the development activities.

Such arrangements generally include termination provisions in the event either party decides that, for strategic or other reasons, it does not wish to pursue the alliance. In many of our agreements, particularly feasibility studies, we are precluded from disclosing the identity of the partner and/or of the molecule(s) with which we are collaborating. A summary of our major existing agreements is provided below. Where agreements provide for the possibility of future payments, there can be no assurance that the payments contemplated under these agreements will be paid, either at all or in part. Future payments are contingent upon a number of factors, such as clinical, regulatory and market success, that are subject to numerous risks and uncertainties. Due to the uncertainties associated with development and commercialization activities in the pharmaceutical industry generally and our business in particular, contemplated payments are neither indicative of the likelihood of receipt of such payments nor of a consistent or predictable future revenue stream.

Digna Biotech SL

In June 2011, we announced that we entered into a joint development agreement for the pre-clinical and clinical development of multiple products with Digna Biotech SL, a joint venture between the Center for Applied Medical Research of the University of Navarra in Pamplona, Spain, and a consortium of private Spanish investors that is focused on developing pipeline products to license to pharmaceutical companies. Under the agreement, we are entitled to a share of out-licensing revenues on the molecules being developed.Digna Biotech SL is a clinical stage biotech company that has developed 3 molecules to clinical phase in six years. The agreement has been structured to leverage Digna's research, preclinical and clinical development efforts, and our formulation expertise utilizing Medusa® and Micropump®. We will be primarily responsible for the formulation and manufacturing process development and Digna will be primarily responsible for the preclinical and clinical development. The three initial Digna products that have been identified for development under the agreement are P144, P17, and Methylthiadenosine (MTA). All of these molecules have shown significant activity in preclinical studies involving multiple indications with high unmet medical need. Both companies expect that the achievement of clinical proof of concept data under the joint development agreement could result in significant additional value creation for the parties. In January 2013, the companies discontinued their efforts on MTA as a result of a gene toxicology issue with the molecule.

Eagle Pharmaceuticals

We announced in October 2011 that we entered into a license and development agreement with Eagle Pharmaceuticals for the development of a Medusa-based hydrogel depot formulation of the small molecule antibiotic, tigecycline. Eagle Pharmaceuticals is a specialty pharmaceutical company. The license agreement was signed after receiving positive pre-clinical results in an initial feasibility study, Under the terms of the license and development agreement, we expect to receive up to $1.2 million (€0.9 million) in milestone payments upon certain development and commercial events and, upon commercial sales, double-digit royalty payments. Additionally, we are entitled to receive a percentage of any sub-licensing revenues received by Eagle Pharmaceuticals. All development expenses are the sole responsibility of Eagle Pharmaceuticals.

GlaxoSmithKline

We began work with GSK on a Micropump formulation of Coreg in 2003 when we entered into a license agreement for use of our Micropump platform for an extended release formulation of carvedilol phosphate. The product was approved by the FDA in October 2006 and launched in March 2007. Prior to 2011, we produced Coreg CR microparticles on a cost plus basis pursuant to a separate supply agreement that expired on December 31, 2010. In October, 2011, we announced that we signed a new supply agreement with GSK for the production of Coreg CR microparticles and remain the sole supplier of Coreg CR microparticles for GSK. Under the agreement, we will receive guaranteed minimum payments to supply Coreg CR microparticles over a minimum period of five years. No earlier than January 1, 2013, GSK may terminate the agreement at their sole discretion by giving six months written notice. The agreement defines the manufacturing relationship between the two companies following the expiration of the previous supply agreement on December 31, 2010. Pursuant to the agreement, we received a payment of €1.3 million ($1.8 million) during the third quarter of 2011 and a further €1.3 million ($1.8 million) payment in the fourth quarter of 2011, as well as a higher margin on all product produced by Flamel for GSK since January 1, 2011. To date, we have received $23 million in milestone payments from GSK and are eligible to receive an additional $2 million if certain milestones are achieved. In 2012, we recognized royalty revenue of $6.9 million on sales of Coreg CR. We are eligible to receive low to mid single digit royalty payments on net sales of Coreg CR. This agreement expires on the later of: (a) ten (10) years from the date of the first commercial sale of product in such country, or (b) the expiration of the last to expire Flamel patent right in such country.

Merck Serono

In December, 2007, we entered into a relationship with Merck Serono to develop a controlled release formulation of an already-marketed Merck Serono product using our Medusa technology platform. In February, 2009, Merck Serono exercised its option to enter into a development and license agreement for this program and paid an upfront fee of € 5.0 million ($6.5 million). Under the terms of the agreement, we are eligible to receive up to €41 million ($53 million) in milestone payments upon certain agreed-upon development events and royalties ranging from the mid- to high- single digits as a percentage of product sales. In March 2012, we announced the completion of the Phase 1 Study conducted by Merck Serono in connection with the development and license agreement for a long-acting, controlled release subcutaneously-administered formulation of interferon beta-1a using the Medusa platform ("IFN-beta XL"). In November 2012, we received notice from Merck Serono that it has decided to terminate for convenience its development and license agreement with Flamel for IFN-beta XL. Unfortunately, we believe that while the Medusa platform was progressing, the IFN-beta XL product's profile and its development timelines no longer met Merck Serono's commercial needs.

Theralpha, SAS

In May 2011, we entered into a joint development program with Theralpha, SAS for a Medusa®-enabled, long-acting formulation of Theralpha's THA-902. THA902 is a natural peptide that is a potent and highly specific Acid Sensing Ion Channel 3 (ASIC 3) inhibitor. It is effective in inflammatory pain animal models following subcutaneous injection and has a number of possible indications, including post-operative pain, osteoarthritis pain and fibromyalgia. The development agreement has been structured to leverage Theralpha's pioneering intellectual property regarding Acid Sensing Ion Channels (ASICs) and Flamel's expertise in creating fully bioactive long-acting formulations of peptides, proteins, and other biologics. Pursuant to the joint development agreement, we enjoy proprietary rights with respect to the formulation. This agreement is part of the initiative that we are pursuing to create more favorable economics for our development programs.

Undisclosed specialty pharmaceutical company (Trigger Lock formulation of pain drugs)

In April 2011, we announced that we had entered into a development and license agreement with an undisclosed specialty pharmaceutical company for the development and commercialization of two molecules for pain indications. We will design formulations of two controlled release Schedule II drugs. Pursuant to the agreement, we received a $3 million license upfront payment, and are eligible to receive between $4.8 and $5.7 million in development-based milestone payments, and mid-single digit royalties upon eventual sale of the product. Future milestone and royalty payments are inherently uncertain and there can be no assurance that these payments will be paid, either at all or in part. Our partner will pay for all manufacturing and regulatory costs, as well as sales and marketing. The formulations will incorporate Trigger Lock attributes, which are designed to substantially defeat a broad range of commonly used tampering techniques. If they are approved, the formulations may be deemed therapeutically equivalent to already-marketed products, meaning that, in most states, they could be substituted by a pharmacist for the already marketed product, as a generic drug.

Undisclosed specialty pharmaceutical company (Micropump formulation of marketed drug)

In May, 2011 we entered into a license and development agreement with an undisclosed specialty pharmaceutical company for the development of a Micropump-enabled, once-daily formulation of a drug that is currently being marketed by that company. Pursuant to the agreement, we received a $0.5 million up-front payment and are entitled to a $1.5 million payment upon approval as well as low to mid-single digit royalty payments upon commercial sales of the product. Our partner will pay for all manufacturing and regulatory costs, as well as sales and marketing.

Manufacturing

The manufacturing facilities for our drug delivery platform are located in Pessac, France, near Bordeaux. These facilities provide us with two commercial scale production lines for the manufacture of Coreg CR microparticles, and another production line used for other Micropump-enabled formulations. The facility has been audited and is approved by the U.S., the European (EMA) and the French regulatory agencies, ANSM (formerly "AFSSAPS") (i.e. the production of certain pharmaceutical products, including commercial quantities of our microencapsulated drugs). Such approval qualifies us to manufacture certain approved pharmaceutical products for sale in most countries in Europe and the U.S.

In the past, in addition to production activities related to our core businesses, we were able to build on our capabilities and experience with GSK and other pharmaceutical customers to engage in toll manufacturing for pharmaceutical partners.

Our Pessac facility equally provides us with one cGMP pilot plant for our Medusa technology. We are able to manufacture qualification batches of our polymers and phase III clinical batches at 10% of the commercial batch size. This facility supports the production of polymer for the needs of our projects based on our Medusa technology

The facility also provides us with non-commercial capabilities for both our Micropump and Medusa technologies. With our experienced workforce and cGMP operations, we are able to perform scale-up activities and clinical batch manufacturing for our Micropump technology and synthesis of new polymers specific to our Medusa formulations.

During 2012, our commercial manufacturing capacity utilization ranged from 50% to 65% of total capacity.

The manufacture of Hycet, marketed by Éclat Pharmaceuticals, is outsourced to a contract manufacturing organization in accordance with a supply agreement that expires in June 2016.

The manufacture of the NDA-submitted products by Éclat is outsourced to contract manufacturing organizations (CMO) in accordance with supply agreements that expire in 2017.

Patents and Proprietary Drug Delivery Platforms

Patents and other proprietary rights are essential to our business. Our contracts are dependent on our technology being patent protected. As a matter of policy, we seek patent protection of our inventions and trademarks and also rely upon trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position.

Generally, we first file a patent application covering an invention in France and in the United States (provisional application). Within one year, we file a U.S. non-provisional patent application for that invention, together with an international patent application, pursuant to the Patent Cooperation Treaty (PCT).

In addition to seeking patent protection in the United States and France, to further protect the inventions that we consider important to the development of our business, from the PCT we will generally prosecute patent applications in Europe, Japan, Canada, and key foreign markets on a selective basis. Therefore, in addition to the above-named countries, we also have patents granted or patent applications pending in a number of other countries, including Mexico, Brazil, China, India, Australia, Israel, South Africa and South Korea.

In selected cases, an invention developed jointly by Flamel Technologies and a partner may be assigned to the partner. The information provided herein, does not include such patent applications.

As of December 31, 2012, we owned approximately 23 U.S. and 366 foreign patents and 34 U.S. and 224 foreign patent applications. Our principal patents include protection for the following:

- The Micropump drug delivery platform is patented under several patents. Among them is Flamel Technologies' key patent, WO 03/030878, which discloses an efficacious coating formulation which provides delayed and sustained release of an active ingredient with absorption limited to the upper part of intestinal tract. This is the basis of the Micropump II technology. It is granted in the United States as US Patent 8,101,209 (Notice of Allowance from the USPTO received on Dec. 12, 2012) and will expire in 2025. It covers Coreg CR formulation and, as such, has been listed at the FDA Orange Book by our partner GSK on February 23, 2012. Equivalent patents are granted in China, Hong Kong, Israel, India, Singapore, Japan, South Korea, Canada, South Africa (expiry in 2022) and in France (expiry in 2021). Patent applications are pending in Brazil, Europe and Mexico and would expire in 2022. The Micropump drug delivery platform is being utilized in collaborations with leading pharmaceutical and biotechnology companies.

- A stable controlled release, ready-to-use suspension, applicable to a large range of active principles which has been issued a patent in the U.S. (US 7,906,145 expires in 2025) and in South Korea, Canada, Israel, Japan, Australia, China, Austria, Belgium, Switzerland, Liechtenstein, Germany, Spain, France, United Kingdom, Italy, Ireland, Luxembourg, Netherlands, Portugal, Sweden, Turkey, India, Mexico, South Africa that expire in 2023. A patent application is pending in Brazil and a continuation application is pending in the US.

- A series of seven patent application families that cover our abuse deterrent technology Trigger Lock™. These patents are pending in the US, Europe, Japan and other countries and will expire between 2025 and 2030.

- The Medusa drug delivery platform is patented under Flamel Technologies' key patents WO 00/30618 and WO 03/104303, granted in the United States and which will expire respectively in 2019 and 2023. They are being utilized in collaborations with leading pharmaceutical and biotechnology companies. Equivalent patents to WO 03/104303 are granted in China, Israel, Mexico, Australia, Japan, South Korea, Canada and South Africa. Patent applications are pending in Brazil, Europe and India. These patents will expire in 2023.

- Medusa® nanogels for delivering proteins and peptides such as insulin, interferon and interleukins, have been issued patents in the US, Australia, China, Israel, Japan, South Korea, Mexico, South Africa and Europe expiring in 2024. Corresponding patent applications are pending in India, Canada, Brazil and Thailand.

- Medusa® microgels for the extended delivery of proteins and peptides have patent applications pending in Europe, Japan, US and other countries. They will expire in 2027 and 2028.

During 2012, we were granted forty-four (44) new patents and filed for one new patent applications with the French Patent Office and the corresponding U.S. provisional patent application.

We can offer no assurance that any patents will provide us with competitive advantages or will not be infringed, challenged, invalidated or circumvented by others, or that the patents or proprietary rights of others will not have an adverse effect on our ability to do business.

There can be no assurance that we will be granted patents in respect of the claims in any of our currently pending or future patent applications, and we can offer no assurance that in the event any claims in any of our issued patents are challenged by one or more third parties, that any court or patent authority ruling on such challenge will determine that such patent claims are valid and enforceable or sufficiently broad in scope to protect our proprietary rights. Also, the nature of the process for obtaining patents and the extent of protection provided by patent laws varies from country to country. We can offer no assurance, therefore, that the issuance to us in one country of a patent covering an invention will be followed by the issuance to us in other countries of patents covering the same invention or that any judicial interpretation of such patents will be uniform in multiple jurisdictions. Furthermore, even if our patents are determined to be valid, enforceable and broad in scope, we can offer no assurance that competitors will not be able to design around such patents.

Government Regulation

The design, testing, manufacturing and marketing of certain new or substantially modified drugs, biological products or medical devices must be approved, cleared or certified by regulatory agencies, regulatory authorities and Notified Bodies under applicable laws and regulations, the requirements of which may vary from country to country. This regulatory process is lengthy, expensive and uncertain. In the United States, the FDA regulates such products under various federal statutes, including the Federal Food, Drug, and Cosmetic Act (FDCA) and the Public Health Service Act. Similar requirements exist in the Member States of the European Union and are imposed by the European Commission and the competent authorities of EU Member States. There can be no assurance that we or our collaborative partners will be able to obtain such regulatory approvals or clearances or certification of conformity on a timely basis, if at all, for any products under development. Delays in receipt or failure to receive such approvals, clearances, , or certifications of conformity, the revocation of previously received approvals or clearances, or certifications of conformity, or failure to comply with existing or future regulatory requirements could have a material adverse effect on our business, financial condition and results of operations.

We believe our delivery platforms, when used in conjunction with therapeutic pharmaceuticals, and development products acquired from Éclat, are subject to drug and biological product approval or marketing authorization requirements. In the United States and the European Union, biological products, such as therapeutic proteins and peptides, generally are subject to the same FDA and EU regulatory requirements as other drugs, although some differences exist. For example, for some biological products a biologic license application (BLA) is submitted for approval for commercialization instead of the new drug application (NDA) or abbreviated new drug application (ANDA) used for other drugs. Also, unlike drug products, some biological products are subject to FDA lot-by-lot release requirements and those approved under a BLA currently cannot be the subject of ANDAs. Insulin, which is regulated as a drug product, typically has not been the subject of ANDAs. However, the FDA is working on a variety of issues pertaining to the possible development of biosimilars and there can be no assurance that this type of submission will continue to be unavailable for insulin. Additionally, our delivery platforms likely will be regulated by the FDA as ‘combination products’ if they are used together with a biologic or medical device. In order to facilitate pre-market review of combination products, the FDA designates one of its centers to have primary jurisdiction for the pre-market review and regulation of both components. In the European Union, applications for marketing authorization of innovative drugs, which are essentially products that are neither generics nor biosimilars, are addressed on a case by case basis by the EMA, followed by a decision of the European Commission, or by the competent authorities of the EU Member States.

New Drug and Biological Product Development and Approval Process

United States and European Union

Regulation by governmental authorities in the United States and other countries is a significant impact in the development, manufacture, and marketing of biological and drug products and in ongoing research and product development activities. The products of all of our pharmaceutical and biotechnology partners as well as our own products, will require regulatory approval by governmental agencies and regulatory authorities prior to commercialization. In particular, these products are subject to manufacturing according to stringent cGMP quality principles, and rigorous, pre-clinical and clinical testing and other pre-market approval requirements by the FDA, the European Commission and regulatory authorities in other countries. In the United States and the European Union,, various statutes and regulations also govern, or influence the manufacturing, safety, labeling, storage, record keeping and marketing of pharmaceutical and biological products. The lengthy process of seeking these approvals, and the subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources.

The FDA and European Union’s statutes, regulations, or policies may change and additional statutes or government regulations may be enacted which could prevent or delay regulatory approvals of biological or drug products. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the U.S. or abroad.

Regulatory approval, when and if obtained, may be limited in scope. In particular, regulatory approvals will restrict the marketing of a product to specific uses. Approved biological and other drugs, as well as their manufacturers, are subject to ongoing review (including requirements and restrictions related to record keeping and reporting, FDA, European Commission and EU Member States competent authorities' approval of certain changes in manufacturing processes or product labeling, product promotion and advertising, and pharmacovigilance, which includes monitoring and reporting adverse reactions, maintaining safety measures, and conducting dossier reviews for marketing authorization renewal). Discovery of previously unknown problems with these products may result in restrictions on their manufacture, sale or use, or in their withdrawal from the market. Failure to comply with regulatory requirements may result in criminal prosecution, civil penalties, recall or seizure of products, total or partial suspension of production or injunction, as well as other actions affecting the commercial prospects of our pharmaceutical and biotechnology partners' potential products or uses or products that incorporate our technologies. Any failure by our pharmaceutical and biotechnology partners to comply with current or new and changing regulatory obligations, and any failure to obtain and maintain, or any delay in obtaining, regulatory approvals, could materially adversely affect our business.

The process for new drug and biological product development and approval has many steps, including:

Chemical and Formulation Development

Pharmaceutical formulation taking into account the chemistry and physical characteristics of the drug or biological substance is the beginning of a new product. If initial laboratory experiments reveal that the concept for a new drug or biological product looks promising, then, a variety of further development steps and tests complying with internationally recognized guidance documents will have to be continued, in order to provide for a product ready for testing in animals and, after sufficient animal test results, also in humans.

Concurrent with pre-clinical studies and clinical trials, companies must continue to develop information about the properties of the drug product and finalize a process for manufacturing the product in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product, and the manufacturer must develop and validate methods for testing the quality, purity and potency of the final products. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product does not undergo unacceptable deterioration over its shelf-life.

Pre-Clinical Testing

Once a biological or drug candidate is identified for development, the candidate enters the pre-clinical testing stage. This includes laboratory evaluation of product chemistry and formulation, as well as animal studies of pharmacology (mechanism of action, pharmacokinetics) and toxicology which may have to be conducted over lengthy periods of time, to assess the potential safety and efficacy of the product as formulated. Pre-clinical tests must be conducted in compliance with good laboratory practice regulations, the Animal Welfare Act and its regulations in the US and the Clinical Trials Directive and related national laws and guidelines in the EU Member States. Violations of these laws and regulations can, in some cases, lead to invalidation of the studies, requiring such studies to be replicated. In some cases, long-term pre-clinical studies are conducted while clinical studies are ongoing.

Investigational New Drug Application

USA: The entire body of chemical or biochemical, pharmaceutical and pre-clinical development work necessary to administer investigational drugs to human volunteers or patients is summarized in an investigational new drug (IND) application to the FDA. The IND becomes effective if not rejected by the FDA within 30 days after filing. There is no assurance that the submission of an IND will eventually allow a company to commence clinical trials. All clinical trials must be conducted under the supervision of a qualified investigator in accordance with good clinical practice regulations to ensure the quality and integrity of clinical trial results and data. These regulations include the requirement that, with limited exceptions, all subjects provide informed consent. In addition, an institutional review board (IRB), composed primarily of physicians and other qualified experts at the hospital or clinic where the proposed studies will be conducted, must review and approve each human study. The IRB also continues to monitor the study and must be kept aware of the study's progress, particularly as to adverse events and changes in the research. Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if adverse events occur. Failure to adhere to good clinical practices and the protocols, and failure to obtain IRB approval and informed consent, may result in FDA rejection of clinical trial results and data, and may delay or prevent the FDA from approving the drug for commercial use.

European Union: The European equivalent to the IND is the Investigational Medicinal Product Dossier (IMPD) which likewise has to contain pharmaceutical, pre-clinical and, if existing, previous clinical information on the drug substance and product. An overall risk-benefit assessment critically analyzing the non-clinical and clinical data in relation to the potential risks and benefits of the proposed trial must also be included. The intended clinical trial must be submitted for authorization by the regulatory authority(ies) of each EU Member States in which the trial is intended to be conducted prior to its commencement. The trial shall be conducted on the basis of the protocol as approved by an Ethics Committee(s) in each EU Member State (EU equivalent to IRBs) before the trial commences. Before submitting an application to the competent authority, the sponsor must register the trial in the EudraCT database where it will be provided with a unique EudraCT number from the EudraCT database.

Clinical Trials

Typically, clinical testing involves the administration of the drug or biological product first to healthy human volunteers and then to patients with conditions needing treatment under the supervision of a qualified principal investigator, usually a physician, pursuant to a 'protocol' or clinical plan reviewed by the FDA- and the competent authorities of the EU Member States along with the IRB or Ethics Committee (via the IND or IMPD submission). The protocol details matters such as a description of the condition to be treated, the objectives of the study, a description of the patient population eligible for the study and the parameters to be used to monitor safety and efficacy.

Clinical trials are time-consuming and costly, and typically are conducted in three sequential phases, which sometimes may overlap. Phase I trials consist of testing the product in a small number of patients or normal volunteers, primarily for safety, in one or more dosages, as well as characterization of a drug's pharmacokinetic and/or pharmacodynamic profile. In phase II, in addition to safety, the product is studied in a patient population to evaluate the product's efficacy for the specific, targeted indications and to determine dosage tolerance and optimal dosage. Phase III trials typically involve additional testing for safety and clinical efficacy in an expanded patient population at geographically dispersed sites. With limited exceptions, all patients involved in a clinical trial must provide informed consent prior to their participation. Meeting clinical endpoints in early stage clinical trials does not assure success in later stage clinical trials. Phase I, II, and III testing may not be completed successfully within any specified time period, if at all.

The FDA and the competent authorities of EU Member States monitor the progress of each clinical trial phase conducted under an IND or IMPD and may, at their discretion, reevaluate, alter, suspend or terminate clinical trials at any point in this process for various reasons, including a finding that patients are being exposed to an unacceptable health risk or a determination that it is unethical to continue the study. The FDA, the European Commission and the competent authorities of EU Member States can also request additional clinical trials be conducted as a condition to product approval. The IRB, the Ethics Committee , and sponsor also may order the temporary or permanent discontinuance of a clinical trial at any time for a variety of reasons, particularly if safety concerns arise. Such holds can cause substantial delay and in some cases may require abandonment of product development. These clinical studies must be conducted in conformance with the FDA's bioresearch monitoring regulations, the Clinical Trials Directive and/or internationally recognized guidance (such as ICH, or International Conference on Harmonization).

New Drug Application or Biological License Application

After the completion of the clinical trial phases of development, if the sponsor concludes that there is substantial evidence that the drug or biological candidate is effective and that the drug is safe for its intended use, an NDA or BLA may be submitted to the FDA. The application must contain all of the information on the drug or biological candidate gathered to that date, including data from the pre-clinical and clinical trials, information pertaining to the preparation of the drug or biologic, analytical methods, product formulation, details on the manufacture of finished products, proposed product packaging, labeling and stability (shelf-life). NDAs and BLAs are often over 100,000 pages in length. If FDA determines that a Risk Evaluation And Mitigation Strategy (REMS) is necessary to ensure that the benefits of the drug outweigh the risks, a sponsor may be required to include as part of the application a proposed REMS, including a package insert directed to patients, a plan for communication with healthcare providers, restrictions on a drug's distribution, or a medication guide to provide better information to consumers about the drug's risks and benefits. Submission of an NDA or BLA does not assure FDA approval for marketing.

The FDA reviews all submitted NDAs and BLAs before it accepts them for filing (the U.S. prerequisite for dossier review). It may refuse to file the application and request additional information rather than accepting an application for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA or BLA to determine, among other things, whether a product is safe and effective for its intended use. As part of this review, the FDA may refer the application to an appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation. There is a strong presumption for advisory committee review for any drug containing an active ingredient not previously approved. The FDA is not bound by the recommendation of an advisory committee. Under the Prescription Drug User Fee Act (PDUFA), submission of an NDA or BLA with clinical data requires payment of a fee. In return, the FDA assigns an action date of 10 months from acceptance of the application to return of a first 'complete response,' in which the FDA may approve the product or request additional information. (Although PDUFA also provides for a six-month "priority review" process, we do not anticipate it applying to any of our products or our partners' products.) There can be no assurance that an application will be approved within the performance goal timeframe established under PDUFA, if at all. If the FDA's evaluation of the NDA or BLA is not favorable, the FDA usually will outline the deficiencies in the submission and request additional testing or information. Notwithstanding the submission of any requested additional information, or even in lieu of asking for additional information, the FDA may decide that the marketing application does not satisfy the regulatory criteria for approval and issue a complete response letter, communicating the agency's decision not to approve the application.

FDA approval of an NDA or BLA will be based, among other factors, on the agency's review of the pre-clinical and clinical data submitted, a risk/benefit analysis of the product, and an evaluation of the manufacturing processes and facilities. Data obtained from clinical activities are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA has substantial discretion in the approval process and may disagree with an applicant's interpretation of the data submitted in its NDA or BLA. For instance, FDA may require us to provide data from additional preclinical studies or clinical trials to support approval of certain development products acquired from Éclat. Among the conditions for NDA or BLA approval is the requirement that each prospective manufacturer's quality control and manufacturing procedures conform to cGMP standards and requirements. Manufacturing establishments often are subject to inspections prior to NDA or BLA approval to assure compliance with cGMPs and with manufacturing commitments made in the relevant marketing application.

Patent Restoration and Exclusivity

The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, establishes two abbreviated approval pathways for drug products that are in some way follow-on versions of already approved products.

Generic Drugs. A generic version of an approved drug is approved by means of an Abbreviated New Drug Application, or ANDA, by which the sponsor demonstrates that the proposed product is the same as the approved, brand-name drug, which is referred to as the "reference listed drug," or RLD. Generally, an ANDA must contain data and information showing that the proposed generic product and RLD (1) have the same active ingredient, in the same strength and dosage form, to be delivered via the same route of administration, (2) are intended for the same uses, and (3) are bioequivalent. This is instead of independently demonstrating the proposed product's safety and effectiveness, which are inferred from the fact that the product is the same as the RLD, which the FDA previously found to be safe and effective. We market Hycet, which is approved under an ANDA held by Mikart, Inc.

505(b)(2) NDAs. If a product is similar, but not identical, to an already approved product, it may be submitted for approval via an NDA under Section 505(b)(2) of the Act. Unlike an ANDA, this does not excuse the sponsor from demonstrating the proposed product's safety and effectiveness. Rather, the sponsor is permitted to rely to some degree on published scientific literature and the FDA's finding that the RLD is safe and effective, and must submit its own data of safety and effectiveness to an extent necessary because of the differences between the products. With regard to certain development products acquired from Éclat, we intend to submit 505(b)(2) NDAs, relying solely on published scientific literature. We do not plan to conduct additional preclinical studies or clinical trials for these 505(b)(2) NDAs.

RLD Patents. An NDA sponsor must advise the FDA about patents that claim the drug substance or drug product or a method of using the drug. When the drug is approved, those patents are among the information about the product that is listed in the FDA publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the *Orange Book*. The sponsor of an ANDA or 505(b)(2) application seeking to rely on an approved product as the RLD must make one of several certifications regarding each listed patent. A "Paragraph III" certification is the sponsor's statement that it will wait for the patent to expire before obtaining approval for its product. A "Paragraph IV" certification is a challenge to the patent; it is an assertion that the patent does not block approval of the later product, either because the patent is invalid or unenforceable or because the patent, even if valid, is not infringed by the new product.

Once the FDA accepts for filing an ANDA or 505(b)(2) application containing a Paragraph IV certification, the applicant must within 20 days provide notice to the RLD NDA holder and patent owner that the application with patent challenge has been submitted, and provide the factual and legal basis for the applicant's assertion that the patent is invalid or not infringed. If the NDA holder or patent owner file suit against the ANDA or 505(b)(2) applicant for patent infringement within 45 days of receiving the Paragraph IV notice, FDA is prohibited from approving the ANDA or 505(b)(2) application for a period of 30 months from the date of receipt of the notice. If the RLD has NCE exclusivity and the notice is given and suit filed during the fifth year of exclusivity, the 30-month stay does not begin until five years after the RLD approval. The FDA may approve the proposed product before the expiration of the 30-month stay if a court finds the patent invalid or not infringed or if the court shortens the period because the parties have failed to cooperate in expediting the litigation.

Regulatory Exclusivities. The Hatch-Waxman Act may provide periods of regulatory exclusivity for products that would serve as RLDs. If a product is a "new chemical entity," or NCE, – generally meaning that the active moiety has never before been approved in any drug – there may be a period of five years from the product's approval during which the FDA may not accept for filing any ANDA or 505(b)(2) application for a drug with the same active moiety. An ANDA or 505(b)(2) application may be submitted after four years, however, if the sponsor makes a Paragraph IV certification challenging a listed patent. Because it takes time for the FDA to review and approve an application once it has been accepted for filing, five-year NCE exclusivity usually effectively means the ANDA or 505(b)(2) application is not approved for a period well beyond five years from approval of the RLD.

A product that is not an NCE may qualify for a three-year period of exclusivity, if the NDA contains clinical data that were necessary for approval. In that instance, the exclusivity period does not preclude filing or review of the ANDA or 505(b)(2) application; rather, the FDA is precluded from granting final approval to the ANDA or 505(b)(2) application until three years after approval of the RLD. Additionally, the exclusivity applies only to the conditions of approval that required submission of the clinical data. For example, if an NDA is submitted for a product that is not an NCE, but that seeks approval for a new indication, and clinical data were required to demonstrate the safety or effectiveness of the product for that use, the FDA could not approve an ANDA or 505(b)(2) application for another product with that active moiety for that use. For example, Coreg CR received three-year exclusivity for the clinical trials that demonstrated the safety and efficacy of the new, controlled-release dosage form; that exclusivity, which has expired, blocked other controlled-release products.

Patent Term Restoration. Under the Hatch-Waxman Act, a portion of the patent term lost during product development and FDA review of an NDA or 505(b)(2) application is restored if approval of the application is the first permitted commercial marketing of a drug containing the active ingredient. The patent term restoration period is generally one-half the time between the effective date of the IND and the date of submission of the NDA, plus the time between the date of submission of the NDA and the date of FDA approval of the product. The maximum period of restoration is five years, and the patent cannot be extended to more than 14 years from the date of FDA approval of the product. Only one patent claiming each approved product is eligible for restoration and the patent holder must apply for restoration within 60 days of approval. The United States Patent and Trademark Office, or PTO, in consultation with the FDA, reviews and approves the application for patent term restoration. When any of our products is approved, we intend to seek patent term restoration for an applicable patent when it is appropriate.

Other Marketing Exclusivity

Pediatric Exclusivity. Section 505A of the FDC Act provides for six months of additional exclusivity and patent protection if an NDA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data does not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or Orange Book listed patent protection cover the drug are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve an ANDA or 505(b)(2) application owing to regulatory exclusivity or listed patents. Coreg CR received such pediatric exclusivity, which extended the three-year new clinical trial exclusivity it previously obtained, as well as the protection of the listed patents. The statutory provision permitting the award of pediatric exclusivity expires on October 1, 2012, and there can be no guarantee that Congress will reauthorize this provision, or do so without significant changes.

Other Countries

Whether or not FDA approval has been obtained, approval of a pharmaceutical product by regulatory authorities must be obtained in any other country prior to the commencement of marketing of the product in that country. The approval procedure may vary from country to country, can involve additional testing, and the time required may differ from that required for FDA approval. Under European Union legislation, product authorization is granted for an initial period of five years. The authorization may subsequently be renewed for an unlimited period on the basis of a re-evaluation of the risk-benefit balance by the competent authorizing authority. In the EU, marketing authorization of drugs is according to either a centralized, decentralized or mutual recognition procedure, generally depending on the nature and type of drug. Certain designated drugs may be authorized only in accordance with the centralized procedure by the European Commission following an opinion by the European Medicines Agency (EMA). The centralized procedure is mandatory for pharmaceutical products developed by means of biotechnological processes (recombinant DNA, controlled expression of genes coding, hybridoma and monoclonal antibody methods), products containing new actives substances indicated for the treatment of AIDS, cancer, diabetes and neuro-degenerative diseases, orphan designated medicinal products and advanced therapy products. Other pharmaceutical products may be authorized in accordance with the centralized procedure where it is demonstrated that they contain new active substances or are demonstrated to have a significant therapeutic benefit, or where they constitute a scientific or technical innovation, or are in the interest of patients at Community level. Where authorization is in accordance with the decentralized or mutual recognition procedures, approval is either by "mutual recognition," whereby the authorization granted by the competent authorities of one EU Member States are recognized by the authorities of other EU Member States, or where the competent authorities of each EU Member State authorize a product on the basis of an identical dossier, with one national authority taking care of the dossier intensively and coordinating activities. To the extent possible, clinical trials of our products are designed to develop a regulatory package sufficient for the grant of marketing authorization in the EU approval according to the Community Code on medicinal products.

Regulatory approval of prices for certain drugs is required in France and in many other countries outside the United States. In particular, many EU Member States make the reimbursement of a product within the national social security system conditional on the agreement by the seller not to sell the product above a fixed price in that country. Also common is the unilateral establishment of a reimbursement price by the national authorities, often accompanied by the inclusion of the product on a list of reimbursable products. Related pricing discussions and ultimate governmental approvals can take several months to years. Some countries require periodic pricing updates and renewals at intervals ranging from two to five years. Some countries also impose price freezes or obligatory price reductions. We cannot assure you that, if regulatory authorities establish lower prices for any product incorporating our technology in any one EU Member State, this will not have the practical effect of requiring our collaborative partner correspondingly to reduce its prices in other EU Member States. We can offer no assurance that the resulting prices would be sufficient to generate an acceptable return on our investment in our products.

Regulation of Combination Drugs

Medical products containing a combination of drugs or biological products may be regulated as 'combination products' in the United States. A combination product generally is defined as a product comprising components from two or more regulatory categories (e.g., drug/device, device/biologic, drug/biologic). Each component of a combination product is subject to the requirements established by the FDA for that type of component, whether a drug, biologic or device.

To determine which FDA center or centers will review a combination product submission, companies may submit a request for assignment to the FDA. Those requests may be handled formally or informally. In some cases, jurisdiction may be determined informally based on FDA experience with similar products. However, informal jurisdictional determinations are not binding on the FDA. Companies also may submit a formal Request for Designation to the FDA Office of Combination Products. The Office of Combination Products will review the request and make its jurisdictional determination within 60 days of receiving a Request for Designation.

In order to facilitate pre-market review of combination products, the FDA designates one of its centers to have primary jurisdiction for the pre-market review and regulation of both components. The determination whether a product is a combination product or two separate products is made by the FDA on a case-by-case basis. It is possible that our delivery platforms, when coupled with a drug, biologic or medical device component, could be considered and regulated by the FDA as a combination product.

If the primary mode of action is determined to be a drug, the product will be reviewed by the Center for Drug Evaluation and Research (CDER) either in consultation with another center or independently. If the primary mode of action is determined to be a medical device, the product would be reviewed by Center for Devices and Radiological Health (CDRH) either in consultation with another center, such as CDER, or independently. In addition, FDA could determine that the product is a biologic and subject to the jurisdiction of the Center for Biologic Evaluation and Research (CBER), although it is also possible that a biological product will be regulated by CDER.

In the European Union, drug combinations, that is, drug products containing two or more drug substances each of which has to contribute a proven advantage of therapy (e.g., synergism, less adverse reactions), are subject to drug regulations like all others. Products combining drug substances or drugs with a device may be subject to device and/or drug regulations, or may be classified as medical devices, depending on the individual case.

Marketing Approval and Reporting Requirements

If the FDA approves an NDA or BLA, the product becomes available for physicians to prescribe. The FDA may require post-marketing studies, also known as phase IV studies, as a condition of approval to develop additional information regarding the safety of a product. These studies may involve continued testing of a product and development of data, including clinical data, about the product's effects in various populations and any side effects associated with long-term use. After approval, the FDA may require post-marketing studies or clinical trials, as well as periodic status reports, if new safety information develops. These post-marketing studies may include clinical trials to investigate known serious risks or signals of serious risks or identify unexpected serious risks. Failure to conduct these studies in a timely manner may result in substantial civil fines and can result in withdrawal of approval.

In addition, the FDA may require distribution to patients of a medication guide or impose other requirements under a REMS for prescription products that the agency determines pose a serious and significant health concern in order to provide information necessary to patients' safe and effective use of such products.

In the European Union, the marketing authorization of a medicinal product may be made conditional on the conduct of phase IV post-marketing studies. Failure to conduct these studies in relation to centrally authorized products can lead to the imposition of substantial fines. Moreover, phase IV studies are often run by companies in order to obtain further information on product efficacy and positioning on the market in view of competitors and to assist in application for pricing and reimbursement.

Post-Marketing Obligations

Any products manufactured and/or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including recordkeeping requirements, reporting of adverse experiences with the product, submitting other periodic reports, drug sampling and distribution requirements, notifying the FDA and gaining its approval of certain manufacturing or labeling changes, complying with certain electronic records and signature requirements, submitting periodic reports to the FDA, maintaining and providing updated safety and efficacy information to the FDA, and complying with FDA promotion and advertising requirements.

Drug and biologics manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and to list their products with the FDA. The FDA periodically inspects manufacturing facilities in the United States and abroad in order to assure compliance with the applicable cGMP regulations and other requirements. Facilities also are subject to inspections by other federal, foreign, state or local agencies. In complying with the cGMP regulations, manufacturers must continue to expend time, money and effort in recordkeeping and quality control to assure that the product meets applicable specifications and other post-marketing requirements. Failure of the Company or our licensees to comply with FDA's cGMP regulations or other requirements could have a significant adverse effect on the Company's business, financial condition and results of operations.

Also, newly discovered or developed safety or efficacy data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, additional pre-clinical or clinical studies, or even in some instances, revocation or withdrawal of the approval. Violations of regulatory requirements at any stage, including after approval, may result in various adverse consequences, including the FDA's delay in approving or refusal to approve a product, withdrawal or recall of an approved product from the market, other voluntary or FDA-initiated action that could delay or restrict further marketing, and the imposition of civil fines and criminal penalties against the manufacturer and NDA or BLA holder. In addition, later discovery of previously unknown problems may result in restrictions on the product, manufacturer or NDA or BLA holder, including withdrawal of the product from the market. Furthermore, new government requirements may be established that could delay or prevent regulatory approval of our products under development, or affect the conditions under which approved products are marketed.

The Food and Drug Administration Amendments Act of 2007 provides the FDA with expanded authority over drug products after approval. This legislation enhances the FDA's authority with respect to post-marketing safety surveillance, including, among other things, the authority to require additional post-marketing studies or clinical trials, labeling changes as a result of safety findings, registering clinical trials, and making clinical trial results publicly available.

In the European Union, stringent pharmacovigilance regulations oblige companies to appoint a suitably qualified and experienced Qualified Person resident in the European Economic Area, to prepare and submit to the competent authorities adverse event reports within specific time lines, prepare Periodic Safety Update Reports (PSURs) and provide other supplementary information, report to authorities at regular intervals and take adequate safety measures agreed with regulatory agencies as necessary. Failure to undertake these obligations can lead to the imposition of substantial fines.

Biologics Price Competition and Innovation Act of 2009

The Hatch-Waxman construct applies only to conventional chemical drug compounds, sometimes referred to as small molecule compounds approved under an NDA. On March 23, 2010, however, the Biologics Price Competition and Innovation Act of 2009, or BPCIA, was signed into law. It creates an abbreviated approval pathway for biological products that are "biosimilar" to a previously approved biological product, which is called the "reference product." This abbreviated approval pathway is intended to permit a biosimilar product to come to market more quickly and less expensively than if a "full" BLA were submitted, by relying to some extent on FDA's previous review and approval of the reference product to which the proposed product is similar. If a proposed biosimilar product meets the statutory standards for approval (which include demonstrating that it is highly similar to the reference product and there are no clinically meaningful differences in safety, purity or potency between the products), the proposed biosimilar may be approved on the basis of an application that is different than the standard BLA. In addition, a biosimilar product may be approved as interchangeable with the reference product if the proposed product application meets standards intended to ensure that the biosimilar product can be expected to produce the same clinical result as the reference product.

The BPCIA provides exclusivity periods during which a product approved under a BLA cannot be relied on as a reference product. No biosimilar application may be submitted to FDA for a period of four years after the reference product was approved, and no biosimilar application may be approved until twelve years after the reference product's approval. If pediatric studies are performed and accepted by the FDA, the twelve-year exclusivity period will be extended for an additional six months. Additionally, the first biosimilar product approved as interchangeable with a reference product will be granted an exclusivity period of varying length, depending on the factual circumstances. Because the BPCIA is a highly complicated statute that has only recently been enacted, there is uncertainty as to how many important components of the new law will be implemented. Some issues may be resolved by three draft guidances that FDA issued in February 2012 or by issuance of regulations or other guidances, but other positions may develop on an ad hoc basis as the FDA confronts them in the context of specific applications.

Regulation of Medical Devices

United States

In the United States, medical devices are classified into Class I, II or III on the basis of the controls deemed by the FDA to be reasonably necessary to ensure their safety and effectiveness. Class I devices are subject to general controls (e.g., labeling, and adherence to cGMPs) and Class II devices are subject to special controls (e.g., performance standards, postmarket surveillance, patient registries, and FDA guidelines). Generally, Class III devices are those which must require premarket approval by the FDA to ensure their safety and effectiveness (e.g., life-sustaining, life-supporting and implantable devices or those found not to be substantially equivalent to legally marketed devices).

Other Countries

The marketing of medical devices in the EU is governed by a variety of EU legislative provisions and related guidance documents commonly referred to as MEDDEVs, the consequences of which depend on the intended use and the classification of the device. Although medical devices are not subject to authorization by the national authorities of EU Member States, manufacturers must ensure that the device complies with Essential Requirements established in applicable EU legislation with respect to design, safety, performance and manufacture. Medical Devices are, in addition, often subject to existing or future national regulation on pricing and reimbursement, which varies from country to country.

The manufacturer of a medical device cannot add a CE mark, which is a mandatory mark for medical devices sold in the EU, to the device unless the devices are demonstrated to comply with the obligations concerning safety and performance requirements of the EU medical device legislation. For devices other than those falling within Class I, the manufacturing facility and the medical device must undergo conformity assessment by a notified body in order to demonstrate compliance. The nature of this assessment will depend on the class of the product. Once all the necessary conformity assessment tasks have been completed, the notified body shall issue certificates of conformity, and the CE Mark may be affixed on the medical devices concerned by its manufacturer as that term is defined in applicable EU legislation. Although EU Member States must accept for marketing medical devices bearing a CE Marking without imposing further requirements related to product safety and performance, national regulatory authorities who are required to enforce compliance with requirements of the EU medical device legislation may restrict, prohibit and recall CE Marked medical devices if they consider, on the basis of available information that they are unsafe. EU Member States can impose additional requirements as long as they do not exceed the obligations provided for in EU medical device legislation or constitute technical barriers to trade. They can also dispute the classification of the device chosen by the device manufacturer. Within the EU, pre CE marking compliance for all medical devices must be supported by clinical data of a type and to the extent set out by the EU directives. When the CE mark has been placed on a medical device its manufacturer must comply with a strict vigilance system. This includes establishment of a vigilance reporting system in accordance with the MEDDEVs provided by the European Commission, which are intended to ensure that reportable adverse events are reported to the competent authority, that information is collected and maintained and that regular reporting obligations are fulfilled.

Other Regulation

Controlled Substances Act. Our Trigger Lock technology is designed to control the release of narcotics and other active ingredients subject to abuse. Narcotics are “controlled substances” under the Controlled Substances Act. The federal Controlled Substances Act (CSA), Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, regulates the manufacture and distribution of narcotics and other controlled substances, including stimulants, depressants and hallucinogens. The CSA is administered by the Drug Enforcement Administration (DEA), a division of the U.S. Department of Justice, and is intended to prevent the abuse or diversion of controlled substances into illicit channels of commerce.

Any person or firm that manufactures, distributes, dispenses, imports, or exports any controlled substance (or proposes to do so) must register with the DEA. The applicant must register for a specific business activity related to controlled substances, including manufacturing or distributing, and may engage in only the activity or activities for which it is registered. The DEA conducts periodic inspections of registered establishments that handle controlled substances and allots quotas of controlled drugs to manufacturers and marketers’ Failure to comply with relevant DEA regulations, particularly as manifested in the loss or diversion of controlled substances, can result in regulatory action including civil penalties, refusal to renew necessary registrations, or proceedings to revoke those registrations. In certain circumstances, violations can lead to criminal prosecution. In addition to these federal statutory and regulatory obligations, there may be state and local laws and regulations relevant to the handling of controlled substances or listed chemicals.

cGMP. Current Good Manufacturing Practices (cGMP) rules apply to the manufacturing of drugs and medical devices. Our manufacturing facilities and laboratories are subject to inspection and regulation by French regulatory authorities in accordance with applicable EU provisions governing cGMP and may also be subject to the United States' and other countries' regulatory agencies. Mutual recognition agreements for government inspections exist between the United States, the EU, Canada, Australia and New Zealand.

In addition to regulations enforced by the FDA, we are also subject to French, U.S. and other countries' rules and regulations governing permissible laboratory activities, waste disposal, handling of toxic, dangerous or radioactive materials and other matters. Our research and development involves the controlled use of hazardous materials, chemicals, viruses and various radioactive compounds. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by French, EU, U.S. and other foreign rules and regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated.

Health Care Fraud and Abuse. We are subject to a number of federal and state laws pertaining to health care "fraud and abuse," such as anti-kickback and false claims laws. Under anti-kickback laws, it is illegal for a prescription drug manufacturer to solicit, offer, receive, or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular drug. Due to the breadth of the statutory provisions and the absence of guidance via regulations and that there are few court decisions addressing industry practices, it is possible that our practices might be challenged under anti-kickback or similar laws. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented for payment to third-party payors (such as the Medicare and Medicaid programs) claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Our sales and marketing activities relating to our products could be subject to scrutiny under these laws. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including fines and civil monetary penalties, the possibility of exclusion from federal health care programs (including Medicare and Medicaid) and corporate integrity agreements, which impose, among other things, rigorous operational and monitoring requirements on companies. In addition, similar sanctions and penalties can be imposed upon executive officers and employees, including criminal sanctions against executive officers. As a result of the potential penalties that can be imposed on companies and individuals if convicted, allegations of such violations often result in settlements even if the company or individual being investigated admits no wrongdoing. Settlements often include significant civil sanctions, including fines and civil monetary penalties, and corporate integrity agreements. If the government were to allege or convict us or our executive officers of violating these laws, our business could be harmed. In addition, private individuals have the ability to bring similar actions. In addition to the reasons noted above, our activities could be subject to challenge due to the broad scope of these laws and the increasing attention being given to them by law enforcement authorities. There also are an increasing number of federal and state laws that require manufacturers to make reports to states on pricing, marketing information, and payments and other transfers of value to healthcare providers. Many of these laws contain ambiguities as to what is required to comply with the laws. Given the lack of clarity in laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent authorities.

Healthcare Reimbursement

In both U.S. and foreign markets, sales of our potential products as well as products of pharmaceutical and biotechnology companies that incorporate our technology into their products, if any, will depend in part on the availability of reimbursement by third-party payers, such as government health administration authorities, private health insurers and other organizations. The U.S. market for pharmaceutical products is increasingly being shaped by managed care organizations, pharmacy benefit managers, cooperative buying organizations and large drugstore chains. Third-party payers are challenging the price and cost effectiveness of medical products and services. Uncertainty particularly exists as to the reimbursement status of newly approved healthcare products. There can be no assurance reimbursement will be available to enable us to maintain price levels sufficient to realize an appropriate return on our product development investment. Legislation and regulations affecting the pricing of pharmaceuticals may change before our proposed products are approved for marketing and any such changes could further limit reimbursement for medical products and services.

Competition

We compete with academic laboratories, research institutions, universities, joint ventures, and other pharmaceutical and biotechnology companies, including other companies developing drug delivery platforms or niche brand or generic specialty pharmaceutical products. Some of these competitors are also our business partners. Our Medusa technology competes with technologies from companies such as Ambrx, Enzon, Polytherics, or Prolor Biotech. Numerous companies, such as Acusphere, Supernus or Depomed, develop oral drug delivery platform that can compete with our Micropump technology . LiquiTime (liquid oral controlled-delivery platform) competes with technologies such as those developed by companies like Tris Pharma. With Trigger Lock, we compete with companies seeking to develop abuse-deterrent formulations of scheduled drugs such as Pain Therapeutics or Acura Pharmaceuticals. The Éclat business competes with companies such as Covidien, Hi-Tech, and others.

There are other companies developing sustained release drug delivery platforms and oral delivery platforms. There could be new chemical entities that are being developed that, if successful, could compete against our technologies or products. Among the many experimental therapies being tested in the United States and in Europe, there may be some that we do not now know of that may compete with our drug delivery platforms or products in the future. These chemical entities and new products may turn out to be safer or may work better than our technologies or products. Our collaborators could choose a competing drug delivery platform to use with their drugs instead of one of our drug delivery platforms.

Many of our competitors have substantially greater experience and research and development, manufacturing, marketing, financial and managerial resources than we do. Moreover, there can be no assurance that our competitors will not obtain patent protection or other intellectual property rights that would make it difficult or impossible for us to compete with their products. Furthermore, acquisitions of competing drug delivery companies by large pharmaceutical companies could enhance our competitors' resources. Accordingly, our competitors may succeed in developing competing technologies and products, obtaining regulatory approval and gaining market share for these products more rapidly than we do.

Further, major technological changes can happen quickly in the biotechnology and pharmaceutical industries. Such rapid technological change, or the development by our competitors of technologically improved or different products, could render our drug delivery platforms obsolete or noncompetitive.

Additionally, the competitive nature of our industry could adversely affect market acceptance of our products or the use of our drug delivery platforms. Our products and technologies may not gain market acceptance among physicians, patients, healthcare payers and the medical community. The degree of market acceptance of any product candidate that we develop will depend on a number of factors, including:

- demonstration of its clinical efficacy and safety;
- its cost-effectiveness;
- its potential advantage over alternative treatment methods; and,
- the marketing and distribution support it receives.

Description of Property

Our corporate headquarters and the research center are located in Venissieux, France (a suburb of Lyon) in five adjacent leased facilities totaling approximately 60,000 square feet. One building of approximately 13,000 square feet houses administrative offices and research laboratories, including equipment dedicated to polymer characterization and analytical research. The lease on this facility expires in 2013 and will be renewed. A second facility comprising approximately 13,000 square feet houses equipment dedicated to our Micropump technology has a lease which expires in 2015. The third facility of approximately 1,000 square feet houses our regulatory affairs and the lease expires at the end of 2013. The fourth facility of approximately 6,800 square feet houses analytical laboratories and quality control and the lease expires in 2013 and will be renewed. The fifth facility of approximately 26,000 square feet houses a biological laboratory and research laboratories with equipment for organic synthesis and polymerization, polymer formulation and small scale processing. The lease on this facility expires at the end of 2014.

We own facilities, of approximately 103,900 square feet, located in Pessac France which are housed on a 470,000 square foot lot in an industrial park not far from the Bordeaux airport. The facilities include manufacturing capabilities with spray-coating equipment and a clean room for the synthesis of biopolymers. The facility has been audited by European and U.S. drug agencies and is, we believe, cGMP compliant.

The initial value of the facility is recorded in our financial books at the value of the liabilities corresponding to the retirement indemnities of the plant staff that we assumed at the time of the plant purchase in 1996, plus the additional investments made by us, less the depreciation and appropriate amortization.

In 2004, we invested $10.3 million in a new building which includes 8,600 square feet dedicated to our Medusa technology with a cGMP pilot plant, extended synthesis capacity and increased capacity to manufacture qualification and phase III batches at 10% of the commercial batch size. This facility was successfully inspected by the French Agency (AFSAPPS) in June 2008 and recorded officially as a GMP excipient manufacturing facility.

Our manufacturing facility of approximately 6,800 square feet is used for the manufacture of Coreg CR microparticles for GSK as well as other Micropump enabled formulations and houses two suites of equipment, as well as a dedicated warehouse, analytical control laboratory and a technical area with air compressor units, refrigeration units for solvents, and heat boiler. The buildings associated with the new Micropump facility, which we own directly, were constructed at a cost of $8.2 million, see page F-26 of our consolidated financial statements.

We invested a further $14.7 million, of which a significant proportion was funded by our partner, GSK, in 2008 for the expansion of our Micropump Pilot Development facilities increasing the available area by 14,300 square feet and renovating a further 4,500 square feet. . The new facility houses administrative offices and process development areas which can be utilized for the production of both clinical and commercial batches, thus increasing our production capacity from two lines to three.

We have commercial and administrative activities located in St. Louis, Missouri acquired following the acquisition of Éclat in March 2012. The office space consists of 4,069 square feet, and the lease expires in the last quarter of 2013.

During 2012, we expended $1.1 million on property and equipment.

See “Item 5, *Operations and Financial Review and Prospects*” for more information regarding our investment activities and principal capital expenditures over the last three years.

ITEM 4A. Unresolved Staff Comments

Not applicable

ITEM 5. Operating and Financial Review and Prospects

The following should be read in conjunction with ”Item 3. *Key Information*” and the Company’s Financial Statements and the Notes related thereto appearing elsewhere in this Annual Report. See also “Item 11. *Quantitative and Qualitative Disclosures About Market Risk*”.

Overview

We are a specialty pharmaceutical company with a long history of expertise in drug delivery, focusing on the development of safer and more efficacious formulations, tackling unmet medical needs in the process. We are focusing on (1) the development and licensing of five versatile, proprietary drug delivery platforms (2) the development of novel, high-value products based on our drug delivery platforms and (3) as a result of our acquisition of Éclat the development, approval, and commercialization of niche branded and generic pharmaceutical products in the U.S.

The acquisition of Éclat in March 2012 has resulted in the implementation of a different business model. We blend novel, high-value, internally developed products with our leading drug delivery capabilities and can commercialize niche branded and generic pharmaceutical products in the U.S. This revised strategy, enables us to be less dependent in the future on the often, changing strategies of our partners. We continue to explore development, supply and licensing opportunities for five drug delivery platforms with third parties, but will not rely completely on those partnerships to create revenue and profit opportunities.

Over the course of 2011 and 2012, we have attempted to maintain a diversified revenue stream with pharmaceutical companies across diverse therapeutic areas and for both new and marketed molecules. In 2012 we have conducted a thorough review of our partnership projects and have sought to complement these with products that will be developed in-house, which will in turn provide diversified revenues sources in the future and less reliance on our partners for success in bringing our technology to commercialized products. Revenues generated by Coreg CR remain a significant portion of our revenue and revenues from GSK contributed to 61% of our revenues in 2012. Maintaining a diversified product, project and customer portfolio is critical to our ongoing success and our goal is to retain a steady number of externally funded programs in our pipeline, while developing products in-house and leveraging revenues from the commercialization of niche branded and generic products in the U.S. provided to us by the Éclat acquisition. .

As in previous years, in 2012 our scientists have been dedicated to executing the research programs signed with our partners and fundamental internal research programs, including those for which we have obtained government funding. The majority of these programs are early stage and pre-clinical programs. We have added four internal proprietary products in to our programs in 2012 in addition to our partnered programs and continued fundamental research aimed at improving our drug delivery capabilities and offerings. Over 2012, our external project portfolio has continued to reduce resulting in the decrease in research and development revenues. Discussions on potential license and development agreements are typically a long process, but we remain committed to pursuing discussions with potential partners where we believe our strategies are aligned, our technology can provide value to our partner and our partner is in a position to finance the development and commercialization of the target product.

Operating expenses decreased in 2012 largely as a result of two non-cash line items. The first is a favorable $18.8 million adjustment from the change in fair-value measurement of the liabilities outstanding for the acquisition of Éclat (see note 2 and 16 to the Consolidated Financial Statements) as of December 31, 2012 compared with acquisition date of March 12, 2012. These commitments were valued at acquisition at $50.9 million and are now valued at $31.9 million, based on current information and data, including financial projections related to the potential of the Éclat products, as well as the share price and interest rate in so far as they influence the value of the warrants. The second is an impairment of in-progress R&D assets of $7.2 million, mainly reflecting changes in market opportunities for one of the acquired pipeline products. Absent these items, operating expenses increased due to costs associated with the Éclat business, which were not present in the prior period, and severance and legal costs generated at the time of the acquisition of Éclat. Our investment in research and development, or R&D, has marginally increased as we pursue the development of the Éclat product portfolio and maintain our research efforts on our in-house product portfolio and partner portfolio. We continue to maintain an aggressive approach to cost controls and are committed to challenging our costs on non-core activities. As projects advance to later stage development we expect to see an increase in R&D expenditure, including regulatory costs and the payment of FDA filing fees, which are expected to be $2 million for each of the Éclat products we expect to file for approval in the next twelve months. Non-cash expenses relative to stock based compensation, amounted to $3.0 million in 2012 and $2.8 million in 2011.

In 2012, our investment in property and equipment was comparable with 2011, since investments were limited to our day to day needs.

As in previous years, the majority of the Company's expenses were incurred in Euros, since the Company's base of operations is in France. However, a portion of revenues were, and will continue to be, denominated in U.S. dollars, see "Item 11. Quantitative and Qualitative Disclosures about Market Risk". Although our reporting currency is the U.S. dollar, the Company's functional currency is the Euro. Conversion of the Company's financial accounts to U.S. dollars for reporting purposes is calculated in accordance with the value of the Euro to the U.S. dollar. See "Item 3. Key Information – Exchange Rates". As such, the Financial Statements are translated as follows: (1) asset and liability accounts at year-end rates, (2) income statement accounts at quarterly weighted average exchange rates for the year (3) cash flow statement quarterly weighted average exchange rates for the year, and (4) shareholders' equity accounts at historical rates. Consequently, the variation in the Euro relative to the U.S. dollar has an impact on the interpretation of the financial statements, which may differ from the underlying variations in the functional currency. For example, the weakening of the Euro relative to the U.S. dollar has resulted in a 7.6% decrease in the average value of the Euro relative to the US dollar between 2011 and 2012. Consequently, Euro denominated expenses will appear to have decreased by an equivalent amount year on year simply as a result of the translation from Euro to U.S. dollars for reporting purposes. The closing value of the Euro relative to the U.S. dollar has increased by 2.0% resulting in a corresponding increase in amounts represented in the balance sheet as of December 31, 2012, compared with December 31, 2011. The Company does not engage in substantial hedging activities with respect to the risk of exchange rate fluctuations, although it does, from time to time, purchase Euros against invoiced Dollar receivables. There is no outstanding hedging agreement as of December 31, 2012.

In certain instances we may compare expenses from one period to another in this Annual Report on Form 20-F using comparable currency exchange rates in order to assess our underlying performance before taking into account exchange fluctuations. To present this information, prior period expenses are converted into U.S. dollars at current year average exchange rates rather than exchange rates for the prior fiscal year. For example, if SG&A expenses were €9.4 million in each of fiscal year 2012 and fiscal year 2011, we would report $12.1 million of SG&A expenses in fiscal year 2012 (based on the quarterly weighted average exchange rates during 2012) and $13.0 million in fiscal year 2011 (based on the quarterly weighted average exchange rates during 2011). The presentation using comparable currency exchange rates would translate the fiscal 2011 expenses using the fiscal 2012 exchange rates and indicate that underlying expenses were flat rather than increasing by $0.9 million, as would be reported in the financial statements under U.S. GAAP. We use figures prepared on a comparable currency basis for internal analysis and communicate similarly externally from time to time, since we believe this appropriate in order to analyze variations in expenditure from one period to another. However, figures provided on a comparable currency basis are unaudited and are not measurements under U.S. GAAP.

Flamel's business is subject to substantial risks, including the uncertainties associated with the research and development of new products or technologies, the length and uncertainty linked to the results of clinical trials and regulatory procedures, uncertainties relating to collaborative arrangements with large companies, difficulties in the scale-up and manufacturing of its products, the uncertainty relating to the market acceptance of new products based on its technologies and uncertainties arising from the Éclat acquisition and the development and commercialization of its portfolio of products. The time required for the Company to achieve sustained profitability, and consequently, the amount of future losses, is highly uncertain. Operating losses may also fluctuate from quarter to quarter as a result of differences in timing of revenues recognized or expenses incurred. See "Item 3. *Key Information - Risk Factors*".

The Company has incurred substantial losses since its inception, and through December 31, 2012, had an accumulated deficit of approximately $192.6 million. Flamel expects to maintain its investment in its research and development activities in line with the internal and external project portfolio, while being vigilant to ensure that investments in non-core activities are limited. Thus, there can be no assurance that the Company will not continue to incur losses. The Company intends to pursue a strategy whereby three distinctive sources of revenue covering the short term, the mid-term and the long term will be pursued as opposed to one source of revenue from collaborative agreements, as was the case a year ago. The acquisition of Éclat in March 2012 has resulted in an altered business model allowing the Company to blend novel, high-value internally developed products with its leading drug delivery capabilities and to commercialize niche branded and generic pharmaceutical products in the U.S. The company will be less dependent in the future on the often, changing strategies of its partners and while it continues to explore development, supply and licensing opportunities for its drug delivery platforms with third parties, these will not be the sole source of revenue and profit opportunities. We expect our research and development costs to increase as we pursue the development of our own products. We raised debt financing in February 2013 to support the development, regulatory approval and, if approved, commercial launch, of products currently under development by Éclat. We currently have two product approval requests with the FDA, one of which was accepted in October 2012, with a PDUFA date of May 2013, and the second, which was filed in February 2013, which is awaiting FDA acceptance. If approved we anticipate generating revenue streams on these products in 2013 and beyond, which will be supplemented by further products from the Éclat business in 2014. Revenues from these products are expected to provide the necessary funds to pursue the development of our internal product portfolio.

Critical Accounting Policies

Revenue Recognition

Revenue includes upfront licensing fees, milestone payments for R&D achievements, compensation for the execution of research and development activities.

Before January 1, 2011, we evaluated arrangements with multiple elements in accordance with Accounting Standards Codification, or ASC, 605-25 Revenue Recognition – Multiple-Element Arrangements. In October 2009, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2009-13 Revenue Arrangements with Multiple Deliverables, or ASU 2009-13, which amended the accounting standards for certain multiple element revenue arrangements to:

- provide updated guidance on whether multiple elements exist, how the elements in an arrangement should be separated, and how the arrangement consideration should be allocated to the separate elements;
- require an entity to allocate arrangement consideration to each element based on a selling price hierarchy, also called the relative selling price method, where the selling price for an element is based on vendor-specific objective evidence ("VSOE"), if available; third-party evidence ("TPE"), if available and VSOE is not available; or the best estimate of selling price ("BESP"), if neither VSOE nor TPE is available; and
- eliminate the use of the residual method and require an entity to allocate arrangement consideration using the selling price hierarchy.

The revenue allocated to each element is then recognized when the basic revenue recognition criteria are met for that element. On January 1, 2011, we adopted ASU 2009-13 on a prospective basis. The adoption of this new guidance did not have any material impact on our consolidated financial statements.

Where agreements have more than one deliverable, a determination is made as to whether the license and R&D elements should be recognized separately or combined into a single unit of account in accordance with ASU 2009-13, Revenue with Multiple Deliverables**.**

The Company uses a Multiple Attribution Model, referred to as the milestone-based method:

- As milestones relate to discrete development steps (i.e. can be used by the co-development partners to decide whether to continue the development under the agreement), the Company views that milestone events have substance and represent the achievement of defined goals worthy of the payments. Therefore, milestone payments based on performance are recognized when the performance criteria are met and there are no further performance obligations.
- Non-refundable technology access fees received from collaboration agreements that require the Company's continuing involvement in the form of development efforts are recognized as revenue ratably over the development period.
- Research and development work is compensated at a non-refundable hourly rate for a projected number of hours. Revenue on such agreements is recognized at the hourly rate for the number of hours worked as the research and development work is performed. Costs incurred under these contracts are considered costs in the period incurred. Payments received in advance of performance are recorded as deferred revenue and recognized in revenue as services are rendered.

The Company recognizes revenue from product sales when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed and determinable, and collectability is reasonably assured.

The Company receives royalty revenues under a license agreement with a third party that sells products based on technology developed by the Company. There are no future performance obligations on the part of the Company under this license agreement. The license agreements provide for the payment of royalties to the Company based on sales of the licensed product. The Company records these revenues based on actual sales that occurred during the relevant period and classifies these revenues in 'Other Revenues'.

The Company receives revenue under signed feasibility study agreements. Revenue is recognized over the term of the agreement as services are performed.

The Company receives financial support for various research and investment projects from governmental agencies. Revenue from conditional grants related to specific development projects is recognized as an offset to operating expenses when all conditions stated in the grant have been met and the funding has been received. Revenue from unconditional grants for research and development projects are recognized as an offset to research and development expense on a pro-rata basis over the duration of the program. Funding can be received to finance certain research and development projects which are repayable on commercial success of the project. In the absence of commercial success, the Company is released of its obligation to repay the funds and the funds are recognized in the Income Statement as 'Other Income'.

The Company receives financial support for capital investment programs from partners. Revenue from these operations is amortized on a pro-rata basis over the expected life of the related assets and reflected as an offset of the depreciation of the related assets in the consolidated statement of operations.

The Company benefits from tax credits on a percentage of eligible research and development costs. These tax credits can be refundable in cash and are not contingent upon future taxable income. As explained in note 4 to the Consolidated Financial Statements, the company determined that the research tax credit should be classified as a research and development grant and the tax credit is recognized as an offset to research and development expense.

Research and Development Costs

R&D expenses are comprised of the following types of costs incurred in performing R&D activities: salaries, allocated overhead and occupancy costs, clinical trial and related clinical manufacturing costs, and contract and other outside service fees. Research and development expenditures are charged to operations as incurred.

Generally, the Company's research and development efforts are either funded internally or by third-party partners. The Company's research and development efforts are organized to allow internal services to support both internal research programs and a variety of partner-sponsored research programs simultaneously, reflecting the Company's approach and belief that internal projects can benefit from the research and development efforts funded by partners and vice versa. Due to this approach, the Company views research and development costs as a whole across the organization and by technological platform. The Company monitors progress on the basis of the actual number of hours/days worked and the cost of outside services for pre-clinical and clinical activities.

Translation of Financial Statements

The reporting currency of the Company is the U.S. dollar and the functional currency of the Company is the Euro. As such, the Financial Statements are translated for reporting purposes as follows: (1) asset and liability accounts at year-end rates, (2) income statement accounts at weighted average exchange rates for the year, and (3) shareholders' equity accounts at historical rates. Corresponding translation gains or losses are recorded in shareholders' equity.

Results of Operations

Years Ended December 31, 2012, 2011 and 2010

Operating Revenues

The Company had total revenues of $26.1 million in 2012, $32.6 million in 2011 and $37.1 million in 2010. The following table shows revenues attributable to license and research activities in millions of US dollars:

		2010	2011	2012
LICENSE AND RESEARCH REVENUES		**19.7**	**10.6**	**9.3**
RESEARCH		**10.9**	**6.3**	**5.1**
Research	Merck Serono	4.1	2.4	-
	Baxter International	0.4	0.0	-
	Pfizer	0.3	0.1	-
	Eagle Pharmaceuticals	-	0.3	0.7
	Undisclosed Partners	6.1	3.5	4.4
LICENSES		**8.8**	**4.3**	**4.3**
Upfront Payment	Merck Serono	1.3	1.4	2.7
	Baxter International	1.6	0.9	-
	Pfizer	0.2	0.7	-
	Undisclosed Partners	0.3	1.3	1.3
	Milestones Merck Serono	5.4	-	-
	Undisclosed Partners	-	-	0.3
TOTAL		**19.7**	**10.6**	**9.3**
	Merck Serono	10.8	3.8	2.7
	Baxter International	2.0	0.9	0.0
	Pfizer	0.5	0.8	0.0
	Eagle Pharmaceuticals	0.0	0.3	0.7
	Undisclosed Partners	6.4	4.8	5.9

In 2012, license and research revenue totalled $9.3 million. License and research revenue in 2011 and 2010 totalled $10.6 million and $19.7 million, respectively. In 2011 research and development revenue totalled $6.3 million and license revenue totalled $4.3 million. In 2010 research and development revenue totalled $10.9 million and license revenue totalled $8.8 million. License and research revenues in 2012 and 2011 have decreased compared with 2010 due to limited milestones. Certain of our key programs have been in clinical development in 2011 and 2012 and as such required less research and development resources. Certain of such programs are awaiting decisions from partners as to the next development stage and in November 2012, Merck Serono informed the Company of its decision to terminate, for convenience, the development and license agreement.

Research and development revenues in 2012 consisted primarily of $0.7 million from Eagle Pharmaceuticals and $4.4 million from undisclosed partners. Research and development revenues in 2011 consisted primarily of $2.4 million from Merck Serono, $0.1 million from Pfizer, $0.3 million from Eagle Pharmaceuticals and $3.5 million from undisclosed partners. Research and development revenues in 2010 consisted primarily of $4.1 million from Merck Serono, $0.4 million from Baxter International, $0.3 million from Pfizer, and $6.1 million from undisclosed partners.

License revenues in 2012 consisted primarily of $2.7 million from Merck Serono (amortization of up-front payments) and $1.6 million from undisclosed partners. License revenues in 2011 consisted primarily of $1.4 million from Merck Serono (amortization of up-front payments), $0.9 million from Baxter International (amortization of up-front payments), $0.7 million from Pfizer (amortization of up-font payment) and $1.3 million from undisclosed partners. License revenues in 2010 consisted primarily of a $6.7 payment million from Merck Serono, including a $5.4 million milestone payment and $1.3 million amortization of up-front payment, and $1.6 million from Baxter International (amortization of up-font payment).

In 2012, product sales and services revenues totaled $9.7 million, $13.4 million in 2011 and $8.2 million in 2010. In 2011 and 2010 product sales relate solely to sales of Coreg CR microparticles to GSK. In 2012, product sales include sales of Coreg CR microparticles to GSK and product sales of Hycet for a total of $0.6 million. Revenues from the sale of Coreg CR microparticles have decreased in 2012 as a result of the lower demand and the fact that a new supply agreement was concluded in 2011 generating favorable terms including two payments each of €1.3 million ($1.8 million) in connection with fluctuation in demand requirements, of which $0.9 million was recognized as revenue in 2012. The multi-year supply agreement provides for fixed unit pricing, as opposed to a cost-plus arrangement in the previous supply agreement, and guaranteed minimal payments minimum period of five years. No earlier than January 1, 2013, GSK may terminate the agreement at its sole discretion by giving six months written notice.

Other revenues of $7.1 million in 2012, $8.6 million in 2011 and $9.2 million in 2010, , consisted primarily of royalties from GSK related to the sale of Coreg CR and to a lesser extent royalties from Corning related to the sale of photochromic lenses that incorporate technology licensed from Flamel.

Operating Expenses

The Company had total costs and expenses of $34.5 million in 2012, $42.2 million in 2011, and $46.9 million in 2010.

The terms of acquisition of Éclat Pharmaceuticals in March 2012 included the issuance of a $12 million note, whose repayment is tied to the approval and net sales of certain Éclat products, 3.3 million warrants and earn-out payments based on the gross profit achieved on the Éclat products (see note 2 to the Consolidated Financial Statements). These commitments are revalued and reassessed at each balance sheet date based on information and data available at that time, including financial projections related to the potential of the Éclat products, as well as the share price and interest rate in so far as they influence the value of the warrants. A favorable $18.9 million adjustment was realized in 2012 from the updated fair-value measurement of these liabilities compared with their valuation at the time of acquisition. In addition, a $7.2 million charge was recognized to reflect the impairment of acquired R&D assets, mainly reflecting changes in market opportunities occurring post-acquistion for one of the acquired pipeline products. Absent these line items operating expenses amounted to $46.1 million in 2012.

As in previous years, in 2012 the majority of costs were incurred on research and development. R&D costs totaled $26.1 million in 2012, $25.1 million in 2011 and $28.7 million in 2010. At comparable currency exchange rates, research and development costs increased by $2.9 million in 2012 compared with 2011, of which $3.5 million relates to expenses for development and regulatory costs of the Éclat portfolio, not present in the prior year.

Our total research and development expenditures can be disaggregated in the following significant type of expenses ($USD in millions):

	2010	2011	2012
Salaries and employee benefits	17.8	16.9	16.5
Materials and Supplies	4.7	3.9	3.4
Pre-clinical, Clinical, Regulatory and Manufacturing outside services	3.4	2.5	3.9
Grants and R&D Tax credit	(8.5)	(7.8)	(6.7)
Depreciation of facilities and equipment	2.4	2.0	1.7
Other Expenses & Taxes	7.7	6.4	6.2
Stock-based Stock Compensation	1.2	1.2	1.1
Total	**28.7**	**25.1**	**26.1**

The resources allocated to each technological platform over the past three years are as follows:

Full Time Equivalents	2010	2011	2012
Medusa	95	87	78
Micropump	37	35	45

The cost of outside services borne by the Company for pre-clinical, clinical, contract manufacturing and regulatory activities by technological platform over the past three years are as follows ($USD in millions):

		2010	2011	2012
Pre-Clinical	Medusa	2.1	1.7	0.4
	Micropump		0.3	
Clinical	Medusa	0.8	0.2	0.3
	Micropump	0.4	0.3	
Contract Manufacturing	Éclat	-	-	1.7
Regulatory	Éclat	-	-	1.5

As of December 31, 2012, Flamel had total research tax credits receivable of $20.3 million. In 2012 the Company obtained an advance secured against the tax credit generated in 2011 valued at $5.8 million as of December 31, 2012. This advance would normally have been received as a cash payment of $6.5 million in 2015. In 2011 the Company obtained an advance secured against the tax credit generated in 2010 valued at $6.8 million as of December 31, 2012. The Company earned a research and development credit of $6.5 million in 2012, $6.1 million in 2011 and$7.7 million in 2010. The tax legislation will enable the Company to benefit from immediate reimbursement of the 2012 tax credit since it meets the SME (Small and Medium Enterprises) criteria under EU legislation as of December 31, 2012.

The average number of employees dedicated to research and development activities has decreased year over year. This decrease was driven by the reduction of the external project portfolio and by the fact that a number of projects are in clinical development, thus requiring less resource allocation. Total employees as of December 31, 2012 amounted to 256 compared with 267 at the end of 2011 and 291 at the end of 2010. The Company has spent $0.7 million on pre-clinical and clinical studies in 2012 compared with $2.5 million in 2011 and $3.4 million in 2010. This reduction is predominantly due to the absence of any spending on Micropump in 2012, since certain projects are being evaluated by partners, and a reduction in pre-clinical spending on Medusa projects as management has reprioritized project development efforts and refocused innovative opportunities to expand the technological platforms. Costs are expected to increase in the future. In 2012, costs of $3.2 million have been incurred on the Éclat portfolio for contract manufacturing services and regulatory activities. These costs are associated with the development of products with outside contractors and costs for preparation of the FDA filing, including meetings with the agency at key points in the development program.

Costs of products and services sold were $5.9 million in 2012, $6.3 million in 2011 and $6.9 million in 2010. These costs relate primarily to the supply of commercial quantities of microparticles of Coreg CR to GSK and the availability of relevant production capacity. In 2012, costs have continued to decline in line with ongoing demand for the product and capacity availability requirements from GSK.

SG&A expenses, amounted to $14.2 million in 2012, $10.8 million in 2011 and $11.3 million in 2010. SG&A expenses included stock based compensation expense of $1.9 million in 2012, $1.2 million in 2011 and $1.8 million in 2010. SG&A expenses in 2012 include Éclat-related expenses of $2.0 million not present in prior periods. Excluding these additional expenses, SG&A expenses increased by $2.0 million over 2011 expenses at comparable currency exchange rates. This increase is due to legal costs and severance costs incurred as a consequence of the acquisition of Éclat in March 2012 and the change in Chief Executive Officer.

Non-Operating Items

Interest income and expense and realized gains on the sale of monetary SICAVs (*Sociétés d'Investissement à Capital Variable*) were an income of $0.5 million in 2012 compared with of $0.6 million in 2011 and $0.4 million in 2010. Total interest income is $0.5 million in 2012, generated on long-term deposits. Interest expense was $118,000 in 2012, $73,000 in 2011 and $24,000 in 2010 and is primarily related to the interest applicable to the Company's equipment leases and, interest incurred on the advance received from Oseo, a French government agency, and secured against future research tax credits (see Note 14.1 to the Consolidated Financial Statements).

Foreign exchange loss was $180,000 in 2012, a gain of $273,000 in 2011 and a gain of $109,000 in 2010. These exchange gains and losses are generated by transactions denominated in foreign currency and in particular revenues denominated in USD. The variation in foreign exchange gain/loss results from the volume of operations in foreign currency and the variation in exchange rates over the year.

Other income in 2012 amounted to $0.1 million as in 2011 and consisted of miscellaneous items, compared with $0.5 million in 2010, which included the write off of a dual customer payment received in 2000 and reimbursement of overpaid taxes from prior years.

Income tax benefit in 2012 amounted to $4.7 million, of which $4.8 million reflects tax benefit of statutory net operating losses generated by the Éclat business. In 2010, the French government modified the tax legislation with respect to the calculation of business tax. In the past, business tax was calculated based on the rental value of property and equipment with a maximum liability based on 3.5% of gross profits. As of 2010, part of the business tax is based on the rental value of property and a part on gross profits. This change in tax legislation has generated tax expense of $0.1 million in 2012, $0.2 million in 2011 and $0.2 million in 2010 relative to the portion of business tax based on gross profit.

As of December 31, 2012, the Company had $184.7 million in French net operating loss carry-forwards and $9.8 million in US net operating losses carry-forwards. The French carry-forwards can be utilized against future operating income indefinitely, subject to an annual limitation of €1.0 million and 50% of taxable income in excess of this threshold and the US carry-forwards can be utilized against future operating income subject to a limitation of $1.8 million per year on pre-acquisition tax losses of $4.9 million.

Net Income/Loss

For the year ended December 31, 2012, the Company reported a net loss of $3.2 million or $0.13 per share, excluding the impact of the re-measurement of the fair value of acquisition liabilities and the impairment of R&D assets the net loss is $14.9 million or $0.59 per share. For the year ended December 31, 2011, Company reported a net loss of $8.8 million or $0.36 per share. For the year ended December 31, 2010, the Company reported a net loss of $9.0 million or $0.37 per share.

Liquidity and Capital Resources

On December 31, 2012, the Company had $2.7 million in cash and cash equivalents and $6.4 million in marketable securities compared with $3.5 million in cash and cash equivalents and $21.0 million in marketable securities on December 31, 2011 and $8.2 million in cash and cash equivalents and $23.2 million in marketable securities on December 31, 2010. The decrease in the level of cash and cash equivalents and marketable securities results from the funding of ongoing operations and the reduction in revenues due to termination of certain projects.

Net cash used in operating activities was $23.1 million as of December 31, 2012, compared with $10.3 million as of December 31, 2011, and $5.5 million as of December 31, 2010. As of December 31, 2012 net cash used in operating activities reflected a net loss of $3.2 million, offset by non-cash movements of $11.2 million, including $18.8 million of remeasurement of acquisition liabilities, $7.2 million of impairment of assets, $4.8 million tax benefit which will be set off against future taxable income, $3.2 million of depreciation on property and equipment, $3.0 million relative to stock compensation expense and $1.0 million of grants recognized to the income statement. The decrease in cash generated from operating activities is driven by the increase in noncash movements and an increase in working capital requirements. The latter results from an increase the R&D tax credit whose reimbursement is deferred, and the absence of upfront payments decreasing deferred revenue. Essentially the decrease in cash provided from operating activities is due to the fall in revenues year and year, absence of new license and development agreements generating upfront payments, while operating expenses have increased.

Net cash provided by investing activities was $15.4 million in 2012, compared with net cash used of $0.4 million in 2011. Investing activities included proceeds from the sale of marketable securities for $18.2 million and purchase of marketable securities for $3.6 million. In 2011 and 2012, the Company has maintained the same investment policy and the sale and purchase of marketable securities are limited to the financing of ongoing operations. In 2012, $1.1 million was spent in the purchase of property and equipment compared with $1.9 million in 2011. In 2012, $1.8 million of cash was acquired following the acquisition of Éclat in March, 2012. Net cash provided by investing activities amounted to $6.0 million in 2010 and included $3.6 million in the purchase of property and equipment, including funding of investments to consolidate our chemistry laboratory at Pessac and create a development laboratory for formulation activities at Pessac as our projects progress into clinical development.

Net cash provided by financing activities was $7.0 million in 2012 and includes an advance of $5.7 million received in the second quarter of 2012 from Oseo, secured against the research and development tax credit of $6.1 million earned in 2011, funding in the form of grants and reimbursable loans received from various government agencies, for a total of $1.0 million. Cash provided by financing activities was 6.1 million in 2011 and included an advance of $7.4 million received in the second quarter of 2011 from Oseo, secured against the research and development tax credit of $7.7 million earned in 2010, funding in the form of grants received from various government agencies, for a total of $0.4 million and reimbursement of an advance from Oseo of ($1.9) million, secured against the 2007 research tax credit. Net cash used by financing activities was ($0.8) million in 2010 and included reimbursement of an advance from Oseo, of ($1.9) million, secured against the 2006 research tax credit and grants received from various government agencies, for a total of $0.4 million.

Since its inception, the Company's operations have consumed substantial amounts of cash and may continue to do so. In February 2013, the Company received funding of $14.5 million in relation to a Facility and Royalty agreement signed with Deerfield entities effective December 31, 2012. The Company believes that ongoing research and product development programs are adequately funded for the next year and believe current working capital to be sufficient for the Company's present requirements. The Company also believes current financial resources and cash from various grants, royalty payments, licenses and commercialization of products currently awaiting FDA approval will be sufficient to meet the Company's cash requirements in the near future. We believe we have sufficient funds to finance operations and cash requirements for at least the next twelve months.

As of December 31, 2012, the Company held marketable securities classified as available-for-sale and recorded at fair value. Total marketable securities totaled $6.4 million at December 31, 2012 and $21.0 million at December 31, 2011.

As of December 31, 2012, the Company had loans of $2.8 million from Oseo, $1.9 million advance from the French Ministry of Industry for a 'Proteozome' research project, These loans do not bear interest and are repayable only in the event that the research is successful technically or commercially. In 2011, the Company reached an agreement with Oseo in relation to funds received in the 1990's for the development of Asacard, for a debt waiver of $0.4 million and reimbursement of $0.5 million over four years, of which $0.1 million was reimbursed in 2012. (See Note 16 to the Consolidated Financial Statements). The Company has evaluated the debt due for the purchase of Éclat Pharmaceuticals at $31.9 million as of December 31, 2012. The obligations relative to the acquisition arise from the $12 million senior note issued by our U.S. subsidiary, Flamel US Holdings, Inc., that is guaranteed by us and our subsidiaries and secured by the membership interests and assets of Éclat and the commitment by Flamel US Holdings, to pay to all gross profit generated by Hycet® up to a maximum of 1 million USD and 20% of any gross profit generated by certain Eclat launch products. See *Item 10. Additional Information – Material Contracts* and *Note 16 – Long Term Debt* for more information regarding these obligations.

In 2004, Flamel and GSK entered into a four year supply agreement whereby Flamel agreed to supply GSK with commercial supplies of product. The provisions of the agreement include payments to Flamel of $20.7 million to support the costs and capital expenditure relative to the creation of a manufacturing area for the production of commercial supply of the product. The capital expenditure consists of both buildings and fixtures, and production equipment. Flamel has immediate title to the building and fixtures and title to production equipment vests with GSK for the duration of the supply agreement.

If the Company breaches the supply agreement through gross negligence, GSK can choose to terminate the supply agreement. In the event of a breach and a decision to terminate the agreement, all payments received become repayable to GSK and Flamel will receive immediate title to all production equipment.

Upon cessation of the supply agreement, in the normal course, GSK will pass title to all production equipment to Flamel without cost. A total of $8.2 million has been spent on the acquisition of buildings and fixtures and a total of $11.1 million has been spent on behalf of GSK for the purchase of production equipment. All funds initially received for completion of the manufacturing area were used to purchase both equipment and facilities prior to December 31, 2006. The funds received from GSK to finance the acquisition of assets owned by Flamel are classified as a current liability for $0.3 million and as a long term liability for $3.8 million. The total liability is being amortized on a pro-rata basis over the expected life of the related assets and reflected as an offset of the depreciation of the related assets.

In July 2006, the supply agreement was supplemented by an agreement with GSK to partly sponsor the expansion of facilities at Pessac from two lines to three in anticipation of an expected increase in demand for the product. The provisions of the agreement include payments to Flamel of $8.1 million to partially support the acquisition of equipment, building and fixtures to which Flamel has immediate title. GSK has exclusive use of part of the facilities in order to meet demand requirements for a period of time. As of December 31, 2007, all installments due under the agreement were received. As of December 31, 2012 these funds are classified as a current liability for $0.4 million and as a long term liability for $2.5 million. The liability is being amortized on a pro-rata basis over the expected life of the assets and proportionally based on funding received compared with the total value of the related assets. The amortization of the liability is reflected as an offset of the depreciation of the related assets.

In June 2011, the Company obtained an advance from OSEO for $7.4 million secured against the research tax credit due to the Company by the tax authorities for expenditures incurred in 2010, totaling $7.7 million. In June 2012, the Company obtained an advance from OSEO for $5.7 million secured against the research tax credit due to the Company by the tax authorities for expenditures incurred in 2011, totaling $6.1 million. The interest rate applied is the monthly average of the Euro Interbank Offered Rate (EURIBOR) plus 0.9%. As of December 31, 2012 the total liability amounted to $12.7 million and is classified as long term.

The contractual cash obligations of the Company as of December 31, 2012, are as follows:

	Payments Due by Period				
(in thousands of U.S. dollars)	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
Long-Term Debt Obligations (see Note 16)	$ 54,247	$ 3,351	$ 20,311	$ 23,199	$ 7,386
Capital Lease Obligations (see Note 17)	$ 273	$ 87	$ 173	$ 13	-
Operating Leases Obligations (see Note 23.2)	$ 1,834	$ 991	$ 801	$ 41	-
Purchase Obligations	$ 705	$ 130	$ 384	$ 191	-
Other Long-Term Liabilities reflected on the Registrant's Balance Sheet under GAAP (see Note 21)	$ 1,027	-	$ 263	$ 234	$ 530
Total Contractual Cash Obligations	$ 58,086	$ 4,559	$ 21,932	$ 23,678	$ 7,916

Future interest payments included in capital lease obligations amount to a total of $19,000.

Off-Balance Sheet Arrangements

As of December 31, 2012, the Company has no off-balance sheet arrangements.

ITEM 6. Directors, Senior Management and Employees

Directors and Senior Management

The following table sets forth the name and position of the directors of the Company as of December 31, 2012. Michael S. Anderson, former Chief Executive Officer of Éclat, was appointed Chief Executive Officer of the Company, effective March 13, 2012.

Name	Position	Year of Initial Appointment
Stephen H. Willard (1) (4) (5)	Non-Executive Chairman of the Board of Directors	2000
Michael S. Anderson (6)	Chief Executive Officer and Director	2012
Catherine Bréchignac (3)	Director	2011
Guillaume Cerutti (1) (2)	Director	2011
Dr. Francis J.T Fildes (1) (2)	Director	2008
Craig Stapleton (1) (2) (3)	Director	2011
Elie Vannier (2) (3)	Director	2005

(1) Member of the Compensation Committee
(2) Member of the Audit Committee
(3) Member of the Nominating and Corporate Governance Committee
(4) Appointed as a Director in 2001
(5) Chief Executive Officer up to March 12, 2012
(6) Appointed Chief Executive Officer on March 13, 2012

The following table sets forth the name and position of the executive officers and senior management of the Registrant.

Name	Position	Year of Initial Appointment
Michael S. Anderson	Chief Executive Officer	2012
Rafael Jorda	Executive Vice President and Chief Operating Officer	1991
Christian Kalita	Directeur Général Délégué Pharmacien Responsable (Chief Pharmacist)	2005]
Siân Crouzet	Principal Financial Officer	2005
Steven A. Lisi	Senior Vice President, Business and Corporate Development	2012
Gregg Stetsko, Ph.D.	Vice President, Research and Development	2013

The term of office of each of the directors expires at the year 2013 ordinary shareholders meeting. With the exception of Mr. Anderson, all of the directors are independent as defined in NASDAQ Marketplace Rule 5605 (a)(2).

In accordance with French law governing a *société anonyme*, the Company is managed by its Board of Directors and by its *Directeur Général* (Chief Executive Officer), who has full executive authority to manage the affairs of the Company, subject to the prior authorization of the Board of Directors or of the Company's shareholders for certain decisions expressly specified by law. In addition, the *Directeur Général* may submit to the Board of Directors the nomination of one or more, but not more than five (5) *Directeurs Généraux Délégués*.

The Board of Directors reviews and monitors Flamel's business, financial and technical strategies. In addition, under French law, the Board of Directors prepares and presents the year-end French statutory accounts of the Company to the shareholders and convenes shareholders' meetings. French law provides that the Board of Directors be composed of no fewer than three and not more than 18 members. The actual number of directors must be within such limits and may be provided for in the *statuts*, our bylaws, or determined by the shareholders at the annual general meeting of shareholders. The number of directors may be increased or decreased only by decision of the shareholders. No more than a third of directors may be over the age of seventy.

Under French law, a director may be an individual or a legal entity. A legal entity that serves as a director must appoint an individual, as a 'permanent representative,' who represents such legal entity on the Board. There is no limitation, other than applicable age limits, on the number of terms that a director may serve. Directors are elected by the shareholders and serve until the expiration of their respective terms, or until their resignation, death or removal, with or without cause, by the shareholders. Vacancies which exist on the Board of Directors: (i) because of the resignation or death of a director, may be filled by the Board of Directors pending the next shareholders' meeting, if the number of remaining directors after such resignation or death exceeds the minimum number of directors set forth in the Articles of Association; (ii) for whatever reason, must be filled by the Board of Directors within three months of such vacancy, if the number of remaining directors after such vacancy is less than the minimum number of directors set forth in the Articles of Association but exceeds the minimum legal requirement; and (iii) for whatever reason, must be filled immediately at a shareholders' meeting if the number of directors after such vacancy is less than the minimum legal requirement.

The Company's Board of Directors currently consists of seven members, six of whom are outside directors and whom we believe bring broad experience to Flamel:

- Mr. Stephen H. Willard was the Chief Executive Officer through March 12, 2012 and has been Chairman of the Board of Directors of Flamel Technologies SA since June 2012. Prior to being asked to serve as CEO by the Board of Directors in June 2005, Mr. Willard was the Company's Chief Financial Officer and General Counsel;

- Catherine Bréchignac is the Permanent Secretary for the French National Academy of Sciences, former Chairperson of the French National Centre for Scientific Research (CNRS), a member of the American Academy of Arts and Sciences and French Ambassador for Sciences and Technology;

- Guillaume Cerutti is the Chairman and Chief Executive Officer of Sotheby's France, former CEO of the French Directorate General for Competition, Consumer Affairs and Repression of Fraud, (Ministry of Finance and Economy) and currently serves as Chairman of the Board of the 'Institut de Financement du Cinéma et des Industries Culturelles';

- Francis JT Fildes is the former Senior Vice President: Head of Global Development for AstraZeneca, PLC, former Director of ProStrakan Pharmaceuticals PLC and a current Director of Fildes Partners Ltd and a Fellow of the Royal Society of Medicine and the Royal Society of Chemistry;

- The Honorable Craig Stapleton is the former United States Ambassador to France and Director of Carlisle Bank and Lead Director of Abercrombie and Fitch;

- Elie Vannier, is the former Group Managing Director of WALLY, former Chief Operating Officer of GrandVision SA, and a current Director of Ingénico, Famar, Conbipel and Pharmacie Principale;

Board Practices

Non-executive Directors of the Company receive fees for their services and are entitled to subscribe for warrants (as described in Note 19.3 to our Consolidated Financial Statements). Directors' fees and warrants are proposed by the Board of Directors and are submitted for the approval of shareholders at the annual general shareholders' meeting. Non-executive directors are reimbursed, upon request, for expenses incurred in attending Board meetings. Upon termination, no benefits are provided to non-executive directors.

All directors are elected by the shareholders at each ordinary shareholders' meeting approving the annual French statutory accounts of the Company. A quorum of the Board consists of one-half of the members of the Board of Directors, and actions are generally approved by a vote of the majority of the members present or represented by other members of the Board of Directors. The Chairman of the Board does not have the ability to cast a deciding vote in the event of a tie vote. A director may give a proxy to another director, but a director cannot represent more than one other director at any particular meeting. Members of the Board of Directors represented by another member at meetings do not count for purposes of determining the existence of a quorum.

Directors are required to comply with applicable law and Flamel's *statuts*. Under French law, directors are liable for violations of French legal or regulatory requirements applicable to '*sociétés anonymes*', violation of the Company's *statuts* or mismanagement. Directors may be held liable for such actions both individually and jointly with the other directors.

French law requires that companies having at least 50 employees for a period of 12 consecutive months has a *Comité d'Entreprise* (Employee Representation Committee) composed of representatives elected from among the personnel. The Employee Representation Committee was formed in 1997. Two of those representatives are entitled to attend all meetings of the Board of Directors of the Company and shareholders' meetings, but they do not have any voting rights.

The Board has a Compensation Committee comprised of solely independent directors, namely Francis J.T. Fildes (Chairman), Guillaume Cerutti, Ambassador Craig Stapleton, and Stephen H. Willard. The Compensation Committee makes recommendations to the Board on the compensation of the executive officers of the Company, including the Chief Executive Officer. The Board makes the final decisions on compensation. The Board has an Audit Committee comprised of solely independent directors, namely Guillaume Cerutti (Chairman), Francis J.T.Fildes, Ambassador Craig Stapleton, and Elie Vannier. The Audit Committee recommends to the Board the selection of Flamel's independent auditors and reviews the findings of the auditors and operates in accordance with the Audit Committee Charter, which is reviewed annually. The Board has a Nominating and Corporate Governance Committee, composed of solely independent directors, namely Ambassador Craig Stapleton (Chairman), Catherine Bréchignac and Elie Vannier. Each of the Compensation Committee, Audit Committee, and Nominating and Corporate Governance Committee has a written charter. The Audit Committee Charter outlines the roles and responsibilities of the Audit Committee which includes appointment, compensation and oversight of the work of any registered public accounting firm employed by the Company and review of all related party transactions. The Audit Committee also assists the Board in oversight of: (1) the integrity of the financial statements of the Company; (2) the adequacy of the Company's system of internal controls; (3) compliance by the Company with legal and regulatory requirements; (4) the qualifications and independence of the Company's independent auditors; and (5) the performance of the Company's independent and internal auditors. The Company also has an informal Scientific Advisory Board.

The Chief Executive Officer of Flamel has full executive authority to manage the affairs of Flamel and has broad powers to act on behalf of Flamel and to represent Flamel in dealings with third parties, subject only to those powers expressly reserved by law or corporate resolutions of the Board of Directors or the shareholders. The Chief Executive Officer determines, and is responsible for the implementation of the goals, strategies and budgets of Flamel, which are reviewed and monitored by the Board of Directors. The Board of Directors has the power to appoint and remove, at any time, the Chief Executive Officer. The Chief Executive Officer is appointed for a term of one year, expiring at the end of the general shareholders' meeting called to approve the financial statements for the prior financial year.

Compensation of Directors and Officers

During 2012, the amount of compensation paid or accrued for the benefit of executive officers of the Company and its subsidiaries for services in all capacities was $1,405,332 for Stephen H. Willard, which includes cash severance payments of $1.0 million (based on applicable exchange rates) and $481,994 for Michael S. Anderson. On March 13, 2012 Mr. Willard resigned as Chief Executive Officer of Flamel. and Mr. Anderson was appointed as Chief Executive Officer. In the event that Mr. Anderson remains as Chief Executive Officer for at least one year and is terminated by Flamel without just cause, Flamel will pay Mr. Anderson €500,000, subject to his signing a settlement agreement with Flamel.

On June 22, 2012, a shareholders' meeting approved a total amount of annual attendance fees to be allocated to the Board of 225,000 Euros, all of which was subsequently distributed. For the fiscal year 2012 a total amount of 290,000 Euros ($372,824) was paid or accrued for the benefit of non-executives for their services in that capacity. Executive directors do not receive compensation for their service in that capacity.

Executive Officers

The Company's executive officers and senior management includes the following individuals:

Mr. Michael S. Anderson has been Chief Executive Officer of Flamel Technologies SA since his appointment effective on March 13, 2012. He has also served as Chief Executive Officer of Éclat Pharmaceuticals LLC since its creation in November 2010. Previously Mr. Anderson worked for KV Pharmaceuticals as President and CEO of its generic business, ETHEX Corporation and President and CEO of Ther-Rx Corporation, a leader in women's healthcare. Mr. Anderson also has worked for Schein Pharmaceuticals and started his career at A.H Robins.

Mrs. Sian Crouzet has been Principal Financial Officer of Flamel Technologies SA since March 2008. She previously worked as Financial Controller France for McCormick & Company Inc. Mrs. Crouzet also worked five years as an external auditor with Ernst and Young (France and UK). She is a UK Chartered Accountant and a graduate of Bradford University (UK).

Mr. Rafael Jorda has been the Executive Vice President and Chief Operating Officer of Flamel Technologies SA since 2005. . He joined the Company in early 1991. Previously, Mr. Jorda had worked 14 years as a research and development scientist on controlled-released and biopolymers at Rhone-Poulenc. He specializes in chemical engineering and in the structure-property relationships of materials. Mr Jorda is a graduate of "*Ecole Nationale Supérieure de Chimie de Lyon*" (France).

Mr. Christian Kalita has been Responsible Pharmacist, Director of Quality and Regulatory Affairs of Flamel Technologies SA since 2005. He worked previously at Skye Pharma as Director of Quality for Europe. Mr. Kalita also worked at Merck Lipha and Merck generics for 10 years in different roles as Chief Pharmacist, Head of Quality Control Management and Head of Industrial Affairs.

Mr. Steve Lisi was appointed Senior Vice President, Business and Corporate Development in June 2012. Previously, he served as partner at Deerfield Management, a leading global healthcare focused hedge fund, between 2007 and 2012. Prior to that, he was founder and managing member/portfolio manager at Panacea Asset Management LLC (New York) between 2005 and 2007, and healthcare portfolio manager at Millenium Partners (New York) between 2002 and 2005. Between 1994 and 2002, he served as analyst in several companies. Mr. Lisi is a graduate of Pepperdine University (Malibu, California).

Dr. Gregg Stetsko was appointed Vice President, Research and Development in February 2013. Dr. Stetsko has over 30 years of experience in the pharmaceutical business, with roles of increasing responsibility at Sandoz, Sterling Winthrop, Ligand Pharmaceutical, and Amylin, where he was Vice President of Operations and Global Leader for the Amylin-Lilly Exenatide Alliance. More recently, he was Chief Scientific Officer for Eagle Pharmaceuticals and a Principal at Tahoe Consulting. Dr. Stetsko earned a B.S. degree in Pharmacy from the University of Rhode Island and a Ph.D. in Industrial and Physical Pharmacy from Purdue University.

Options to Purchase Securities from the Company

On June 22, 2012 the shareholders of the Company authorized the creation of a share option plan (the '2012 Plan'), which authorizes the Board of Directors to issue options to subscribe for up to 1,000,000 Shares. The 2012 Plan is designed to permit the granting of 'qualifying stock options' under French tax law principles as well as 'incentive stock options' under the Internal Revenue Code of 1986, as amended. Options granted under the 2012 Plan will have an exercise price based on the market price of the share, in the form of ADS, on NASDAQ, on the day preceding the date of the Board meeting, provided however, that such price is not less than 80% of the average market price for the shares on the NASDAQ, in the form of ADSs, during the last twenty trading days preceding said meeting. In this case, the price of the shares should be equal or superior to 80% of the average market price for the share on NASDAQ, in the form of ADS, during the last twenty trading days preceding such meeting. The options granted under the 2012 Plan are exercisable up to ten years from the date of grant.

On June 22, 2012, the shareholders of the Company authorized the issuance of 200,000 new shares that the Board of Directors was authorized to award and issue free of charge to officers and employees of the Company as compensation for services rendered. Under the terms of the awards, the shares are definitively owned by the beneficiaries two years following their allocation, and the beneficiaries are required to retain the shares for a further two years.

Free Share Awards Granted and Warrants Subscribed from January 1, 2012 to March 31, 2013

	Stock Options	Exercise Price in Euros	Exercise Price in USD (2)	Expiration	Free Share Awards
Anderson	275,000	5.25	6.93	March 2022	35,250
	80,500	3.00	4.07	February 2023	
Bourboulou					5,000
Caisse					3,000
Capelle	5,000	3.00	4.07	February 2023	5,000
Castan					5,000
Chan	7,000	3.00	4.07	February 2023	8,000
Chatellier	7,000	3.00	4.07	February 2023	6,000
Commaret	6,000	3.00	4.07	February 2023	5,000
Constancis	4,000	3.00	4.07	February 2023	3,000
Crouzet	10,000	3.00	4.07	February 2023	10,000
Fendler	7,000	3.00	4.07	February 2023	5,000
Gorria	5,000	3.00	4.07	February 2023	5,000
Greene	4,000	3.00	4.07	February 2023	4,000
Kalita	5,000	3.00	4.07	February 2023	5,000
Keith	7,000	3.00	4.07	February 2023	5,000
Lisi.	275,000	4.09	5.01	July 2022	
	25,000	3.00	4.07	February 2023	2,500
Lemercier	4,000	3.00	4.07	February 2023	3,000
Macke	7,500	3.00	4.07	February 2023	7,000
Meyrueix	7,000	3.00	4.07	February 2023	5,000
Nicolas	4,000	3.00	4.07	February 2023	3,000
Stetsko	100,000	3.00	4.07	February 2023	
Vialas	4,000	3.00	4.07	February 2023	5,000

(2) Historical value at date of grant

Employees

As of December 31, 2012, Flamel had 251 full-time employees. The following table sets forth the average number of employees for each of the last three years based on their principal geographic locations.

Employees

Year End	Venissieux (1)	Pessac (2)	U.S. (3)	Total
2010	157	144	3	304
2011	141	138	3	282
2012	125	131	8	264

(1) Primarily engaged in research activities
(2) Primarily engaged in technical and pharmaceutical development activities and manufacturing
(3) Primarily engaged in administrative, commercial and marketing activities

The Company's future will depend on its ability to attract and retain highly qualified personnel. The Company believes that its employee relations are good. As required by French law, the Company has created an Employee Representation Committee ('*Comité d'Entreprise'*) composed of representatives elected from among the personnel. Two of these representatives are entitled to attend certain meetings of the Board of Directors of the Company, but they do not have any voting rights.

Share Ownership

The following table sets forth the share ownership of directors and executive officers as of the date indicated:

OWNERSHIP OF SHARES AS OF MARCH 31, 2013

Name	Shares Owned	% of Ordinary Shares Outstanding	Warrants	Number of Options	Exercise Price in Euros €	Exercise Price in USD (2) $	Expiration	Free Share Awards	Total	Total %
Vannier	1	0.00%	50,000		4.5	6.29	June 2013			
			50,000		5.44	6.68	June 2014			
			50,000		3.54	5.04	June 2015		150,001	0.50%
Bréchignac	1	0.00%							1	0.00%
Cerutti	1	0.00%	50,000		3.54	5.04	June 2015		50,001	0.17%
Fildes	1	0.00%	50,000		4.5	6.29	June 2013			
			50,000		5.44	6.68	June 2014			
			50,000		3.54	5.04	June 2015		150,001	0.50%
Stapleton	238,014	0.94%	50,000		3.54	5.04	June 2015		288,014	0.96%
Willard	525,000	2.07%		100,000	20.81	25.27	December 2013			
				150,000	14.81	19.70	December 2014			
				100,000	16.23	19.35	December 2015			
				100,000	25.39	33.46	December 2016			
				75,000	4.03	5.17	December 2018			
				100,000	5.06	7.46	December 2019			
				100,000	5.29	7.01	December 2020			
				100,000	3.28	4.39	December 2021		1,350,000	4.52%
Anderson	13,000	0.05%		275,000	5.25	6.93	March 2022			
				80,500	3.00	4.07	February 2023	35,250	403,750	1.35%
Crouzet	34,560	0.14%		49,990	12.86	15.83	September 2015			
				5,000	16.23	19.35	December 2015			
				3,750	25.39	33.46	December 2016			
				10,000	5.06	7.46	December 2019			
				5,000	3.28	4.39	December 2021			
				10,000	3.00	4.07	February 2023	20,000	138,300	0.46%
Jorda	110,369	0.43%		5,000	9.88	11.66	June 2013			
				60,000	14.81	19.70	December 2014			
				105,000	12.86	15.83	September 2015			
				75,000	16.23	19.35	December 2015			
				60,000	25.39	33.46	December 2016			
				50,000	4.03	5.17	December 2018			
				75,000	5.06	7.46	December 2019			
				75,000	5.29	7.01	December 2020			
				75,000	3.28	4.39	December 2021	25,000	715,369	2.39%
Kalita	29,500	0.12%		50,000	16.23	19.35	December 2015			
				6,500	25.39	33.46	December 2016			
				5,000	5.06	7.46	December 2019			
				5,000	5.29	7.01	December 2020			
				5,000	3.28	4.39	December 2021			
				5,000	3.00	4.07	February 2023	10,000	116,000	0.39%
Lisi	-			275,000	4.09	5.01	July 2022			
				25,000	3.00	4.07	February 2023	2,500	302,500	1.01%
Stetsko	-	0.00%		100,000	3.00	4.07	February 2023		100,000	0.33%

(2) Historical value at date of grant

ITEM 7. Major Shareholders and Related Party Transactions

Major Shareholders

The following table sets forth as of March 31, 2013, the percentage of Ordinary Shares owned by Deerfield Capital Management,.and Broadfin Capital, the persons each known to beneficially own more than 5% of the Company's Ordinary Shares. The table set forth below is based on information contained in Schedule 13/Ds or 13/Gs on file with the SEC. Percentages are calculated based on 25,415,400 total shares, which was the total number of shares outstanding as of March 31, 2013.

Identity of Person or Group	Amount of Ordinary Shares Owned	Percentage of Class
Deerfield Capital L.P	4,333,475(1)	17.05%
Broadfin Capital LLC	2,491,261	9.8%

1) Information as to the amount and nature of beneficial ownership was obtained from the Schedule 13G filed with the SEC on December 5, 2012 by Deerfield Capital L.P. and its affiliates ("Deerfield"). Deerfield shares beneficial ownership with Deerfield Special Situations Funds LP in respect of 532,712 Ordinary Shares, Deerfield Private Design Fund II LP in respect of 1,432,534 Ordinary Shares, Deerfield Private Design International II in respect of 1,641,574 Ordinary Shares, and Deerfield Management Company L.P. and Deerfield Special Situations Fund International Limited in respect of all 726,655 Ordinary Shares. Such reported amount excludes warrants to purchase ADSs representing 3,300,000 ordinary shares of Flamel held by Breaking Stick Holdings, LLC (formerly Éclat Holdings), the manager of which is Deerfield Management Company, LP and of which Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. are members. The address of Deerfield is 780 Third Avenue, 37th Floor, New York, New York 10017.
2) Information as to the amount and nature of beneficial ownership was obtained from the Schedule 13G/A filed with the SEC on February 19, 2013 by Broadfin Capital LLC ("Broadfin"). As of the close of business on December 31, 2012, Broadfin beneficially owned 2,491,261 ADRs, (The address of Broadfin is 237 Park Avenue, Suite 900, New York, New York 10017.

The Company's major shareholders do not have different voting rights. To the best of our knowledge, Flamel Technologies is not directly or indirectly owned or controlled by another corporation, by any government, or by any other natural or legal person. We are not aware of any arrangement that may at a subsequent date result in a change of control. As of March 31, 2013, the Company has Ordinary shareholders of record including the Bank of New York. Approximately 96.0% of the Company's outstanding shares are represented by American Depositary Shares (ADS). Approximately 2.91% of the Ordinary Shares are held in France. One record holder resides in France.

Significant changes in the percentage ownership held of record by any of our major shareholders in the last three years, as reported to the SEC, were as follows:

Major Shareholder	Filing Date	Ownership Percentage
BVF, Inc.	February 10, 2010	14.49%
BVF Partners L.P.	February 11, 2011	11.56%
	January 11, 2012	7.84%
	February, 14, 2013	0.85%
Broadfin Capital LLC	September 28, 2012	5.12%
	February 18, 2013	9.80%
Deerfield Capital L.P.	August 31, 2011	4.90%
	December 5, 2011	5.01%
	January 4, 2012	17.05%
O.S.S. Capital Management LP	February 22, 2010	23.52%
Schafer Brothers LLC	March 31, 2010	13.1%
Oscar S. Schafer	February 14, 2011	12.47%
	January 4, 2012	0.0%
Visium Asset Management L.P.	April 9, 2010	7.58%
	February 14, 2011	7.09%
	February 10, 2012	7.74%
	February 14, 2013	0%

Related Party Transactions

In March 2012, we acquired, through our wholly owned subsidiary Flamel US, all of the membership interests of Éclat from Éclat Holdings, an affiliate of our largest shareholder Deerfield Capital L.P., for consideration primarily consisting of a $12 million senior, secured six-year note that is guaranteed by us and our subsidiaries and secured by the equity interests and assets of Éclat, two warrants to purchase a total of 3,300,000 ADSs of Flamel and commitments to make earnout payments of 20% of any gross profit generated by certain Éclat launch products and 100% of the gross profit generated by Hycet® up to a maximum of $1 million. Upon closing of the acquisition, Mr. Anderson, the Chief Executive Officer of Éclat, was appointed Chief Executive Officer of Flamel. See *Item 4. Information on the Company — General Overview — Acquisition of Éclat Pharmaceuticals* for more information about this acquisition. Mr. Anderson retains a minority interest in Éclat Holdings,renamed Breaking Stick, and does not have the ability to control this entity by virtue of his minority interest.

On February 4, 2013, we entered into a Facility Agreement (the “Facility”), through Flamel US with Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (together, the “Deerfield Entities”) providing for debt financing of $15 million by the Deerfield Entities (the “Loan”). The completion of the transaction is subject to the execution of a security agreement on certain receivables and assets.

The Facility is subject to certain limitations, and allows us to use the funds for working capital, including continued investment in our research and development projects. The aggregate principal amount of the Loan of $15 million must be repaid over four years as follows: 10% on July 1, 2014, and 20%, 30% and 40% on the second, third, and fourth anniversary, respectively, of the original disbursement date of the Loan. Notwithstanding the foregoing, the entire principal amount of the Loan may be repaid in whole or in part on any interest payment date occurring after December 31, 2013. Interest will accrue at 12.5% per annum to be paid quarterly in arrears, commencing on April 1, 2013, and on the first business day of each July, October, January and April thereafter. Interest on any late payments will accrue at a rate of 22.5% per annum. Pursuant to the Facility, we were required to pay the Deerfield Entities a fee of $112,500 for entering into the transaction and to reimburse the Deerfield Entities for legal costs and expenses incurred in effecting the transaction.

The Facility also includes certain customary representations and warranties, including that we are conducting our business in compliance with our organizational documents, no default or event of default has occurred under the Facility or certain related documents, Flamel we are generally capable of paying our debts as they become due and we do not have any liens or indebtedness, other than certain liens and debts permitted in the Facility. The Facility also includes certain covenants, indemnification and other customary loan-related provisions.

The Facility provides that we will give the Deerfield Entities notice 30 days prior to the consummation of certain significant transactions or two days following the public announcement of any such transactions, and that the Deerfield Entities may demand final payment of any outstanding balance under the Facility at the time any such transaction is consummated. The Facility also includes certain negative covenants, including restrictions on the activities of our subsidiaries related to major corporate events such as liquidation, business combinations, the formation of partnerships, acquisitions and the creation of liens and indebtedness.

The Facility agreement is attached hereto as Exhibit 4.7 and incorporated herein by this reference.

In conjunction with our entry in the Facility, Éclat entered into a Royalty Agreement with Horizon Santé FLML, Sarl and Deerfield Private Design Fund II, L.P., both affiliates of the Deerfield Entities (together, "Deerfield PDF/Horizon"). The Royalty Agreement provides for Éclat to pay Deerfield PDF/Horizon 1.75% of the net sales price of the products sold by us and any of our affiliates until December 31, 2024, with royalty payments accruing daily and paid in arrears for each calendar quarter during the term of the Royalty Agreement. The Royalty Agreement requires Éclat to take all commercially reasonable efforts to obtain the necessary regulatory approvals to sell the products in the United States and to market the Products after receiving such approvals.

The Royalty agreement is attached hereto as Exhibit 4.8 and incorporated herein by this reference.

We have also entered into a Security Agreement dated February 4, 2013 with Deerfield PDF/Horizon, whereby Deerfield PDF/Horizon was granted a security interest in the intellectual property and regulatory rights related to the products to secure the obligations of Éclat and Flamel US, including the full and prompt payment of royalties to Deerfield PDF/Horizon under the Royalty Agreement. Pursuant to the Security Agreement, Éclat authorized Deerfield PDF/Horizon to file such financing statements, naming Deerfield PDF/Horizon or its designee as secured party and Éclat as debtor, as required in order for Deerfield PDF/Horizon to perfect its security interest as required by Article 9 of the New York Uniform Commercial Code, and Éclat agreed to take any other action reasonably requested by Deerfield PDF/Horizon to cause the attachment, perfection and enforceability of such security interest. The Security Agreement provides that Deerfield PDF/Horizon, upon the request of Éclat, shall promptly release any lien on the collateral under the Security Agreement upon payment and performance of all of its obligations under the Royalty Agreement.

The Security Agreement is is attached hereto as Exhibit 4.8 and incorporated herein by this reference.

We have also entered into two pledge agreements on certain receivables and equipment we own. These agreements are required to be recorded under French law and will be filed pursuant to a Form 6-K upon the completion of official registration in France.

Interests of Experts and Counsel

Not applicable

ITEM 8. Financial Information

Financial Statements

The financial statements contained in this Annual Report begin on page F-1.

Legal Proceedings

While we may be engaged in various claims and legal proceedings in the ordinary course of business, we are not involved (whether as a defendant or otherwise) in and we have no knowledge of any threat of, any litigation, arbitration or administrative or other proceeding that management believes will have a material adverse effect on our consolidated financial position or results of operations.

On November 9, 2007 a putative class action was filed in the United States District Court for the Southern District of New York against the Company and certain of its current and former officers entitled Billhofer v. Flamel Technologies, et al. By Order dated March 8, 2013, the Court granted the Company's motion to dismiss and the action was dismissed with prejudice and costs. The complaint purported to allege claims arising under the Securities Exchange Act of 1934 based on certain public statements by the Company concerning, among other things, a clinical trial involving Coreg CR and seeks the award of damages in an unspecified amount. By Order dated February 11, 2008, the Court appointed a lead plaintiff and lead counsel in the action. On March 27, 2008, the lead plaintiff filed an amended complaint that continued to name the Company and two previously named officers as defendants and asserted the same claims based on the same events as alleged in the initial complaint. On May 12, 2008, the Company filed a motion to dismiss the action, which the Court denied by Order dated October 1, 2009. On April 29, 2010, the lead plaintiff moved to withdraw and substitute another individual as lead plaintiff and to amend the Case Management Order. On June 22, 2010, the lead plaintiff voluntarily agreed to dismiss the action against one of the previously named officers. On September 20, 2010, the Court granted the lead plaintiff's withdraw and substitution motion and the parties proceeded to engage in fact discovery. On March 6, 2012, the Court issued its opinion granting the lead plaintiff's motion for class certification, which was originally filed in October 2010 and opposed by the Company. On July 30, 2012, the Court issued an opinion denying the lead plaintiff's motion, filed on December 15, 2011, to further amend his complaint, which motion sought to substantially revise plaintiff's asserted basis for contending that the defendants should be found liable for the statements at issue. In its opinion, the Court held that the proposed amended complaint failed to properly plead a viable claim.

In May 2011, we announced the filing of a lawsuit in the U.S. District Court for the District of Columbia against Lupin for infringement of our US Patent No. 6,022,562, which is held by the Company and associated with Coreg CR. The lawsuit was dismissed in favor of a lawsuit involving the same parties for infringement of the same patent that was lodged in the U.S. District Court for the District of Maryland in May 2011. GSK is a third party defendant in the Maryland lawsuit. The lawsuit is based on the Abbreviated New Drug Application (ANDA) filed by Lupin seeking permission to manufacture and market a generic version of Coreg CR before the expiration of the patent. In August 2012, the Company concluded a settlement agreement with Lupin and the parties filed a joint stipulation of dismissal on September 11, 2012.

In September 2011, Flamel filed a lawsuit in the U.S. District Court for the District of Maryland against Anchen Pharmaceuticals, Inc., for infringement of the same patent. The lawsuit is based on the ANDA filed by Anchen seeking permission to manufacture and market a generic version of Coreg CR before the expiration of the patent. In May 2012, the Company concluded an agreement whereby Anchen agreed to pay the sum of $400,000 in settlement of the claim.

Dividend Policy

The Company has never declared or paid a cash dividend on any of its capital stock and does not anticipate declaring cash dividends in the foreseeable future.

Significant Changes

In March 2012, the Company acquired all of the membership interests of Éclat, a St. Louis-based specialty pharmaceutical company focused on the development, approval and commercialization of niche branded and generic pharmaceutical products. For more information about this transaction, see 'Item 4. *Information on the Company – General Overview - Acquisition of Éclat Pharmaceuticals*' and 'Item 10. *Additional Information – Material Contracts*'.

ITEM 9. The Offer and Listing

The principal trading market for the Company's securities in ADSs is the NASDAQ Global Market. Each ADS represents one Share, nominal value 0.122 Euros. Each ADS is evidenced by an ADR. The Bank of New York is the Depositary for the ADRs. As of December 31, 2012, there were 24,398,513 ADSs outstanding in the United States and there were 34 holders of ADSs on record. As of December 31, 2012, there were 25,415,400 Shares outstanding.

The following table shows the high and low closing sales prices of the ADSs on the NASDAQ Market for the periods indicated.

	Price Per ADS (U.S.$)	
Year	**High**	**Low**
2008	10.80	3.68
2009	9.67	3.99
2010	9.60	6.02
2011	6.97	3.85
2012	7.67	2.99

	Price Per ADS (U.S.$)	
Quarter Ended	**High**	**Low**
1st Quarter, 2010	9.60	7.52
2nd Quarter, 2010	9.06	6.52
3rd Quarter, 2010	8.00	6.02
4th Quarter, 2010	7.90	6.64
1st Quarter, 2011	6.97	5.82
2nd Quarter, 2011	6.63	5.02
3rd Quarter, 2011	5.44	3.85
4th Quarter, 2011	5.26	4.08
1st Quarter, 2012	7.67	5.11
2nd Quarter, 2012	5.65	4.05
3rd Quarter, 2012	5.50	4.06
4th Quarter, 2012	4.25	2.99
1st Quarter, 2013	4.59	3.25

	Price Per ADS (U.S.$)	
Month Ended	**High**	**Low**
October 31, 2012	4.25	3.76
November 30, 2012	3.88	3.17
December 31, 2012	3.22	2.99
January 31, 2013	4.58	3.25
February 29, 2013	4.03	3.36
March 31, 2013	4.59	3.85

ITEM 10. Additional Information

Memorandum and Articles of Association

For a general description of these documents, see 'Description of Share Capital' in the Company's registration statement on Form F-1, as filed with the U.S. Securities and Exchange Commission on April 19, 1996, registration number 333-03854, which is incorporated by reference. There have been no changes to these documents. No more than a third of the Directors may be over the age of seventy.

Ownership of Shares by Non-European Union Persons

A 'declaration administrative' or administrative declaration is required in The Republic of France to be filed with the French Ministry of the Economy, Finance and the Budget at the time of the acquisition of a controlling interest in Flamel by any non-EU resident or group of non-EU residents acting in concert or by any EU resident controlled by a non-EU resident. With respect to the acquisition (by a EU resident or a non-EU resident) of a controlling interest in a company that could affect 'public health,' the administrative declaration is replaced by a procedure that requires prior declaration of the acquisition to the French Ministry of Economy, Finance and the Budget with the ability for such Ministry to oppose the investment during a one-month period. As it is a pharmaceutical company, the acquisition of a controlling interest in Flamel could be deemed to affect 'public health.'

Under existing administrative rulings, ownership of 20% or more of a listed company's share capital is regarded as a controlling interest, but a lower percentage may be held to be a controlling interest in certain circumstances (such as when the shareholder has the ability to elect members of the board of directors). No administrative declaration is required where an EU resident or group of EU residents acts in concert to acquire a controlling interest in Flamel provided that the acquiring party or parties satisfy the requirements of EU residency.

Under French law, there is no limitation on the right of non-resident or foreign shareholders to vote securities of a French company.

Material Contracts

We have entered into certain material contracts in connection with the Éclat acquisition and debt financing. *See 'Item 7: Major Shareholders and Related Party Transactions'*. The following is a summary of the material terms of these contracts that is qualified in its entirety by reference to the actual documents attached as exhibits to this Annual Report on Form 20-F and for those incorporated by reference herein:

Note Agreement and Note

Under the terms of a Note Agreement among Flamel, Flamel US and Éclat Holdings dated March 13, 2012, Flamel US issued a $12 million senior note to Éclat Holdings that is guaranteed by Flamel and its subsidiaries and secured by the membership interests and assets of Éclat. The note is payable over six years only if certain contingencies are satisfied, namely that: (a) two or more Éclat launch products are approved by the FDA or (b) one Éclat launch product is approved by the FDA and has generated $40 million or more in cumulative net. We refer to these contingencies as Thresholds. If either Threshold is satisfied, Flamel US will pay 25% of the original principal amount due under the note on each of the third, fourth, fifth and sixth anniversaries of the date of the note. The note accrues interest at an annual rate of 7.5%, payable in kind, until one Éclat launch product is approved by the FDA. After FDA approval of one Éclat launch product is obtained, any interest previously capitalized is payable in cash no later than nine months following FDA approval, and any future interest is payable in cash when due.

Warrants to Purchase ADSs

In addition to the note, Flamel also issued to Éclat Holdings, two six-year warrants to purchase an aggregate of 3,300,000 ADSs, each representing one ordinary share, of Flamel. One warrant is exercisable for 2,200,000 ADSs at an exercise price of $7.44 per ADS, and the other warrant is exercisable for 1,100,000 ADSs at an exercise price of $11.00 per ADS. In June 2012, shareholder approval was obtained for issuance of the warrants. . In connection with the issuance of the warrants, Flamel entered into a registration rights agreement with Éclat Holdings dated March 13, 2012, pursuant to which Flamel filed, on September 18, 2012, a registration statement with the SEC covering the resale of the ADSs issuable upon exercise of the warrants.

Facility Agreement

The Facility which is subject to certain limitations, will allow Flamel to use the funds for working capital, including continued investment in its research and development projects. The aggregate principal amount of the Loan must be repaid over four years as follows: 10% on July 1, 2014, and 20%, 30% and 40% on the second, third, and fourth anniversary, respectively, of the original disbursement date of the Loan. Notwithstanding the foregoing, the entire principal amount of the Loan may be repaid in whole or in part on any interest payment date occurring after December 31, 2013. Interest will accrue at 12.5% per annum to be paid quarterly in arrears, commencing on April 1, 2013, and on the first business day of each July, October, January and April thereafter. Interest on any late payments will accrue at a rate of 22.5% per annum. Pursuant to the Facility, Flamel was required to pay the Deerfield Entities a fee of $112,500 for entering into the transaction and to reimburse the Deerfield Entities for legal costs and expenses incurred in effecting the transaction.

Royalty Agreement

The Royalty Agreement, provides for Éclat to pay Deerfield PDF/Horizon 1.75% of the net sales price of the Products sold by Flamel and any of its affiliates until December 31, 2024, with royalty payments accruing daily and paid in arrears for each calendar quarter during the term of the Royalty Agreement. The Royalty Agreement requires Éclat to take all commercially reasonable efforts to obtain the necessary regulatory approvals to sell the Products in the United States and to market the Products after receiving such approvals.

Exchange Controls

The payment of any dividends to foreign shareholders must be effected through an authorized intermediary bank. All registered banks and credit establishments in the Republic of France are authorized intermediaries. Under current French exchange control regulations, there are no limitations on the amount of cash payments that may be remitted by Flamel to residents of the United States. Laws and regulations concerning foreign exchange controls do require, however, that all payments or transfers of funds made by a French resident to a non-resident be handled by an authorized intermediary bank.

Taxation

The following is a discussion of French and U.S. federal income tax consequences of owning and disposing of Flamel Ordinary Shares or Flamel ADSs. This description is only relevant to holders of Flamel Ordinary Shares or Flamel ADSs who are not residents of France and do not hold their shares in connection with a permanent establishment or a fixed base in France through which the holders carry on a business or perform personal services.

This description may not address all aspects of French tax laws that may be relevant in light of the particular circumstances of individual holders of Flamel Ordinary Shares or Flamel ADSs. It is based on the applicable tax laws, regulations and judicial decisions as of the date of this annual report, and on the Convention between the United States of America and the Republic of France for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes on Income and Capital dated as of August 31, 1994 entered into force on December 30, 1995, and the 2004 and 2009 Protocols amending the Treaty, all of which are subject to change, possibly *with retroactive* effect, or different interpretations. This discussion refers to the treaty between the United States and France described above, and the two Protocols together as the ‘Treaty’.

The following discussion should be considered only as a summary and does not purport to be a complete analysis of all potential tax effects of the purchase or ownership of the Flamel Ordinary Shares or Flamel ADSs. This summary does not address all potential tax implications that may be relevant as a holder, in light of particular circumstances.

Tax Consequences to Non-U.S. Holders

The following discussion applies to holders of Flamel Ordinary Shares that are not 'U.S. Holders,' as defined below. Holders of Flamel Ordinary Shares should consult their tax advisor concerning the French tax consequences.

Taxation on Sale or Disposal of Flamel Ordinary Shares

Generally, a holder of Flamel Ordinary Shares will not be subject to any French income tax or capital gains tax when the holder sells or disposes of Flamel Ordinary Shares if all of the following cumulative conditions apply:

- the holder is not a French resident for French tax purposes;
- the holder has held not more than 25% of Flamel's dividend rights, known as *droits aux bénéfices sociaux*, at any time during the preceding five years, either directly or indirectly;
- the holder is not a resident of a non-cooperative jurisdiction as defined below; and
- Flamel is not considered as a real estate company.

If a double tax treaty bet*ween France and the country* of residence of a holder of Flamel Ordinary Shares contains more favorable provisions, a holder may not be subject to any French income tax or capital gains tax when the holder sells or disposes of any Flamel Ordinary Shares, even if one or all of the above statements does not apply to the holder.

Subject to various conditions, foreign states, international organizations and a number of foreign public bodies are not considered as French residents for these purposes.

As from January 1, 2012, transfers of a listed company's shares are subject to French registration or transfer taxes when they are documented by a written deed, irrespective of whether that deed is executed in France or outside of France. A tax credit will be available (up to the extent of the transfer taxes triggered in France) in order to shelter the foreign transfer tax liability (if registration is also required under foreign law). From January 1, 2012 to July 31, 2012, the following rates apply to the transfer of listed company shares: (i) 3% for the portion of the value below €200,000; (ii) 0.5% for the portion of the value between €200,000 and €500,000,000 and; (iii) 0.25% for the portion of the value above €500,000,000. As from August 1, 2012, a unique 0.10% tax rate will apply to the transfer of listed company's shares.

Taxation of Dividends

In France, companies may only pay dividends out of income remaining after tax has been paid.

French companies must, in principle, deduct a 30% withholding tax from dividends paid to non-residents. As from January 1, 2008, the rate of this withholding tax has been reduced to 21% for dividends paid to EU, Norway Iceland and Liechtenstein residents individuals.

In addition, anti-avoidance rules regarding transactions concluded with non-cooperative jurisdictionsprovide that dividends distributed to non-cooperative jurisdictions residents as of March 1, 2010, as per the criteria defined by the French tax code, would be subject to a 55% withholding tax.

The following countries were considered by the French tax authorities as non-cooperative jurisdictions in 2012:

Botswana	Guatemala	Montserrat	Niue
Brunei	Marshall Islands	Nauru	Philippines

Under most double tax treaties between France and other countries, the rate of this withholding tax may be reduced or eliminated in some circumstances. Generally, if dividends are subject to a French withholding tax, a holder who is a non-French resident is subsequently entitled to a tax credit in that holder's country of residence for the amount of tax actually withheld.

However, France has entered into tax treaties with various countries under which qualifying residents are entitled to obtain from the French tax authorities a reduction (generally to 15% or 5%) or an elimination of the French withholding tax.

If these arrangements apply to a shareholder, Flamel will withhold tax from the dividend at the lower rate, provided that the shareholder has established, before the date of payment of the dividend, that the shareholder is entitled to the lower rate and has complied with the filing formalities. Otherwise, Flamel must withhold tax at the full rate of 30% (for other than European Union, Iceland, Norway or Liechtenstein residents individuals) or 21% (for European Union, Iceland, Liechtenstein or Norway residents individuals), and the shareholder may subsequently claim the excess tax paid.

Estate and Gift Tax

France imposes estate and gift tax on shares of a French company that are acquired by inheritance or gift, this tax applying without regards to the residence of the transferor. However, France has entered into estate and gift tax treaties with certain countries pursuant to which, provided that certain conditions are met, residents of the treaty country may be exempt from such tax or obtain a tax credit.

Non-residents should consult their own tax advisors regarding whether French estate and gift tax would apply to them and whether they might be able to claim an exemption or tax credit pursuant to an applicable tax treaty.

Wealth Tax

French individual residents are taxable on their worldwide assets. Non-resident individuals may be subject to French wealth tax (*impôt de solidarité sur la fortune*) only on their assets which are located in France. However, financial investments made by non-resident individuals, other than in real estate companies, are exempt from wealth taxes as long as the individuals own less than 10% of the French company's capital stock, either directly or indirectly, provided that their shares do not enable them to exercise influence on the French company.

Even if these conditions are not satisfied, a non-French resident holder may be exempt from French wealth tax if such holder is entitled to more favourable provisions pursuant to a double tax treaty between France and the holder's country of residence.

Tax Consequences to U.S. Holders

The following is a discussion of the U.S. federal income tax consequences of the ownership and disposition of Flamel Ordinary Shares or Flamel ADSs by a U.S. Holder. For purposes of this discussion a "U.S. Holder" is a beneficial owner of the Flamel Ordinary Shares or Flamel ADSs who is (i) an individual citizen or resident of the United States; (ii) a corporation created or organized in the United States or under the laws of the United States or any political subdivision thereof; (iii) an estate whose income is includible in gross income for United States federal income tax purposes regardless of its source; or (iv) a trust whose administration is subject to the primary supervision of a United States court and over which one or more United States persons have the authority to control all substantial decisions of the trust. This discussion does not apply to a U.S. Holder who is also a resident of France for French tax purposes.

If an entity that is treated as a partnership for United States federal income tax purposes holds Flamel Ordinary Shares or Flamel ADSs, the tax treatment of a partner of such partnership will generally depend on the status of the partner and upon the activities and organization of the partnership. If you are a partner of such a partnership you are urged to consult your tax advisor.

This summary is based in part upon the representations of the custodian and the assumption that each obligation in the Depositary Agreement with the Bank of New York relating to our ADSs and any related agreement will be performed in accordance with its terms.

The following is a general summary of the principal tax effects on U.S. Holders for purposes of U.S. federal income tax and French tax, if all of the following four points apply:

- the U.S. Holder owns, directly, indirectly, or constructively, less than 10% of Flamel's share capital;
- the U.S. Holder is entitled to the benefits of the Treaty (including under the 'limitations on benefits article of the Treaty);
- the U.S. Holder holds Flamel Shares as capital assets; and
- the U.S. Holder's functional currency is the U.S. dollar.

For purposes of the Treaty and the U.S. Internal Revenue Code of 1986, as amended (the "Internal Revenue Code"), Holders of Flamel ADSs will be treated as the owner of the Flamel Ordinary Shares represented by such ADSs.

Special rules may apply to United States expatriates, insurance companies, pass-through entities and investors in such entities, tax-exempt organizations, financial institutions, persons subject to the alternative minimum tax, securities broker-dealers, persons who use the mark-to-market method of accounting for their securities holdings, and persons holding their Flamel Ordinary Shares or Flamel ADSs as part of a conversion or other integrated transaction, among others. Special rules relevant to those holders are not discussed in herein.

Holders of Flamel Ordinary Shares or Flamel ADSs should consult their own tax advisers as to the particular tax consequences to them of owning Flamel Ordinary Shares or Flamel ADSs, including their eligibility for benefits under the Treaty, the applicability and effect of U.S. federal, state, local, non-U.S. and other tax laws and any possible changes in tax law.

Taxation of Dividends

Withholding Tax

Dividends paid to non-residents by French companies are subject to a 30% French withholding tax. Under the Treaty, this withholding tax is reduced to 15% if a U.S. Holder's ownership of Flamel Shares is not effectively connected with a permanent establishment or a fixed base that the U.S. Holder has in France.

Dividends paid to a U.S. Holder by French companies are immediately subject to a reduced rate of 15%, provided that such U.S. Holder establishes before the date of payment that he is a U.S. resident under the Treaty by completing and providing the depositary with a simplified certificate (the "*Certificate*") in accordance with the French tax guidelines (4 J–1-05 released on February 25, 2005). In order to establish U.S. residency for this Certificate, the U.S. resident should submit a Form 8802 (Application for United States Residency Certification) for certification from the U.S. Internal Revenue Service ("*IRS*"). The Form 8802 is used to request Form 6166, a letter of U.S. residency certification for purposes of claiming benefits under an income tax treaty. The application for the Form 8802 requires a non-refundable user fee of $85 USD and should be submitted by mail with the application at least 45 days prior to the date the certification is needed.

Dividends paid to a U.S. Holder that has not filed the Certificate before the dividend payment date will be subject to French withholding tax at the rate of 30%. The tax withheld in excess of 15% can be reclaimed, provided that such U.S. Holder duly completes and provides the French tax authorities with the relevant form described in the tax guidelines mentioned above (the "*Form*") before December 31 of the second calendar year following the year during which the dividend is paid. U.S. Pension Funds (as defined by Sections 401(a), 401(b), 403(b) and 457 of the Internal Revenue Code) and other Tax-Exempt Entities (as defined by Section 501(c) 3) of the Internal Revenue Code) are subject to the same general filing requirements as other U.S. Holders except that they may be required to supply additional documentation evidencing their entitlement to these benefits.

The Certificate and the Form, together with instructions, will be provided by the depositary to all U.S. Holders registered with the depositary. The depositary will arrange for the filing with the French Tax authorities of all Certificates properly completed and executed by U.S. Holders of Shares and returned to the depositary in sufficient time that they may be filed with French Tax authorities before the distribution so as to obtain an immediate reduced withholding tax rate.

U.S. Federal Income Tax.

For U.S. federal income tax purposes, subject to the rules discussed below under the section titled "PFIC Status," the gross amount of a dividend paid by Flamel, including any French tax withheld, will be included in each U.S. Holder's gross income as dividend income when payment is received by them (or the custodian, if the U.S. Holder owns Flamel ADSs), to the extent they are paid or deemed paid out of Flamel's current or accumulated earnings and profits as calculated for U.S. federal income tax purposes.

Dividends paid by Flamel will not give rise to any dividends received deduction. They will generally constitute foreign source "passive" income for "foreign tax credit" purposes. For certain recipients, dividends will constitute foreign source "general" income for foreign tax credit purposes

Under current U.S. federal tax law, as a general matter, amounts distributed as dividends by Flamel with respect to Flamel Ordinary Shares or Flamel ADSs paid in taxable years beginning before January 1, 2013 will be eligible to be treated as "qualified dividend income" that is subject to a U.S. federal income tax at a maximum rate of 15% provided both that certain minimum holding period and other requirements are met (i.e. Flamel meets the requirements of a "qualified foreign corporation" under the US federal income tax rules)and that Flamel is not treated as a PFIC (as defined below under the section titled "*PFIC Status*").

For U.S. federal income tax purposes, the amount of any dividend paid in Euros, including any French withholding taxes, will be equal to the U.S. dollar value of the Euro on the date the dividend is included in income, regardless of whether the payment is in fact converted into U.S. dollars. A U.S. Holder will generally be required to recognize foreign currency gain or loss when the U.S. Holder sells or disposes of the Euros. A U.S. Holder may also be required to recognize foreign currency gain or loss if that U.S. Holder receives a refund under the Treaty of tax withheld in excess of the Treaty rate. This foreign currency gain or loss will generally be U.S. source ordinary income or loss.

To the extent that any dividends paid exceed Flamel's current and accumulated earnings and profits as calculated for U.S. federal income tax purposes, the distribution generally will be treated as follows:

- First, as a tax-free return of capital, to be applied against and reduce in the adjusted basis of a U.S. Holder's Flamel Ordinary Shares or Flamel ADSs. Accordingly, this adjustment will increase the amount of gain, or decrease the amount of loss, which a U.S. Holder will recognize if such U.S. Holder later disposes of those Flamel Ordinary Shares or Flamel ADSs, as the case may be.
- Second, the balance of the dividend in excess of the adjusted basis will be taxed as capital gain recognized on a sale or exchange.

French withholding tax (which, as described above), is imposed on at a rate of 15% under the Treaty generally is treated for U.S. federal income tax purposes as payment of a foreign income tax. A U.S. Holder may take this amount as a credit or deduction against the U.S. Holder's U.S. federal income tax liability. The foreign tax credit is subject to various conditions and limitations, including minimum holding period requirements. Special rules apply in determining the foreign tax credit limitation with respect to dividends that are subject to the maximum 15% tax rate applicable to qualified dividend income.

To the extent a refund of French tax withheld with respect to dividends is available under the Treaty or otherwise under French law, the amount of tax withheld that is refundable will not be eligible for credit against your U.S. federal income tax liability.

Taxation of Capital Gains

French Tax. A U.S. Holder who is a resident of the United States for purposes of the Treaty will not be subject to French tax on any capital gain if such U.S. Holder sells or exchanges its Flamel Ordinary Shares or Flamel ADSs, unless the U.S. Holder has a permanent establishment or fixed base in France and the Flamel Ordinary Shares or Flamel ADSs the U.S. Holder sold or exchanged were attributable to that permanent establishment or fixed base. Special rules apply to individuals who are residents of more than one country.

U.S. Income Tax. In general, for U.S. federal income tax purposes, a U.S. Holder will recognize capital gain or loss if the U.S. Holder sells or exchanges its Flamel Ordinary Shares or Flamel ADSs. Any such gain or loss generally will be U.S. source gain or loss. If a U.S. Holder is an individual, any capital gain will generally be subject to U.S. federal income tax at preferential rates if the U.S. Holder meets applicable minimum holding period requirements.

PFIC Status. Flamel believes that it will not be treated as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes, for the current taxable year or for future taxable years. However, an actual determination of PFIC status is factual and cannot be made until the close of the applicable taxable year. Flamel will be a PFIC for any taxable year in which either:

- 75% or more of its gross income is passive income; or
- its assets which produce passive income or which are held for the production of passive income amount to at least 50% of the value of its total assets on average.

If Flamel were to be treated as a PFIC, the tax consequences applicable to distributions on Flamel Ordinary Shares and Flamel ADSs, and any gains a U.S. Holder realizes when the U.S. Holder disposes of such Flamel Ordinary Shares or Flamel ADSs, may be less favorable to the U.S. Holder. In addition, a U.S. Holder would be required to file Form 8621 with respect to its interest in Flamel. Each U.S. Holder should consult its own tax advisors regarding the PFIC rules and their effect on the U.S. Holder if they purchase Flamel Ordinary Shares or Flamel ADSs.

French Estate and Gift Taxes

Under 'The Convention Between the United States of America and the French Republic for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Estates, Inheritance and Gifts of November 24, 1978,' if a U.S. Holder transfers their Flamel Shares by gift, or if they are transferred by reason of the U.S. Holder's death, that transfer will only be subject to French gift or inheritance tax if one of the following applies:

- the U.S. Holder is domiciled in France at the time of making the gift, or at the time of the U.S. Holder's death; or
- the U.S. Holder used the Flamel Ordinary Shares or Flamel ADSs in conducting a business through a permanent establishment or fixed base in France, or the U.S. Holder held the Flamel Ordinary Shares or Flamel ADSs for that use.

French Wealth Tax

The French wealth tax does not generally apply to Flamel Ordinary Shares or Flamel ADSs if the U.S. Holder is treated as a 'resident' of the United States for purposes of the Treaty. and if the U.S. Holder does not own a substantial interest (*participation substantielle) in Flamel*. Pursuant to article 23 §2 of the Treaty, "an individual is considered to have a substantial interest if he or she owns, alone or with related persons, directly or indirectly, shares, rights, or interests the total of which gives right to at least 25% of the corporate earnings".

Expansion of U.S. Medicare Tax

The U.S. Health Care and Reconciliation Act of 2010 requires that, in certain circumstances, certain U.S. Shareholders that are individuals, estates, and trusts pay a 3.8% tax on "net investment income," which includes, among other things, dividends on and gains from the sale or other disposition of stock, effective for taxable years beginning after December 31, 2012. Prospective investors should consult their own tax advisors regarding this new legislation.

United States Information Reporting and Backup Withholding

Dividend payments made by us (Flamel) to a U.S. Holder in respect of Flamel Ordinary Shares or Flamel ADSs and proceeds from the sale or disposal of a U.S. Holder's Flamel Ordinary Shares or Flamel ADSs may be subject to information reporting to the Internal Revenue Service.

U.S. federal backup withholding generally is a withholding tax (currently imposed at a rate of 28%) on some payments to persons that fail to furnish required information. Backup withholding will not apply to a U.S. Holder who furnishes a correct taxpayer identification number or certificate of foreign status and makes any other required certification, or who is otherwise exempt from backup withholding. Any U.S. persons required to establish their exempt status generally must file Internal Revenue Service Form W-9, entitled Request for Taxpayer Identification Number and Certification. Amounts withheld as backup withholding may be credited against a U.S. Holder's U.S. federal income tax liability. A U.S. Holder generally may obtain a refund of any excess amounts withheld under the backup withholding rules by filing the appropriate claim for refund with the Internal Revenue Service and furnishing any required information within the appropriate amount of time.

Recently Enacted Legislation Related to Disclosure of Information with Respect to Foreign Financial Assets

Recently enacted legislation in the U.S. requires a U.S. Holder that holds an interest in "specified foreign financial assets" to disclose information to the IRS related to these holdings. These new disclosure requirements are effective for taxable years beginning after March 18, 2010, and apply for any year in which the aggregate value of all such holdings is greater than $50,000. For these purposes, "specified foreign financial assets" may include (i) depository or custodial account maintained by foreign financial institutions and foreign investment vehicles, (ii) interests in, or securities issued by, non-U.S. persons, and (iii) other financial instruments or contracts held for investment where the issuer or counterparty is a non-U.S. person. In addition, a U.S. Holder may be required to furnish information to avoid a presumption that the aggregate value of the U.S. Holder's holdings of specified foreign financial assets is in excess of $50,000. A U.S. Holder who fails to comply with these requirements may be subject to penalties. Investors should consult their own tax advisors regarding the effect of this legislation in their particular circumstances.

Documents on Display

Flamel is subject to the informational requirements of the Securities Exchange Act of 1934, as amended, and, in accordance with those requirements, files reports and other information with the U.S. Securities and Exchange Commission. Copies of reports and other information, when so filed, may be inspected free of charge and may be obtained at prescribed rates at the public reference facility maintained by the SEC at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the public reference rooms. You may also access documents filed with the SEC at its website www.sec.gov. Certain of the reports that the Company files with the Commission may be available from time to time on the Company's internet website, at www.flamel.com. Flamel is not incorporating the contents of its or the SEC's websites or the website of any other person into this document.

ITEM 11. Quantitative and Qualitative Disclosures About Market Risk

The Company conducts a portion of its business transactions in U.S. dollars. For the year ended December 31, 2012 revenues denominated in U.S. dollars represented 42% of total revenues. As a result, the Company's financial results could be significantly affected by the fluctuation of the Euro relative to the U.S. dollar. Specifically, 33.6% of the Company's cash and cash equivalents, totalling $2.7 million as of December 31, 2012, and all of the Company's marketable securities, totalling $6.4 million, as of December 31, 2012, are denominated in Euros, as are the vast majority of the Company's expenses. If the dollar were to strengthen by 10% versus the Euro, there would be a corresponding negative effect on these items of $0.7 million in our balance sheet. Conversely, if the dollar were to weaken by 10% versus the Euro, there would be a positive effect on these items of $0.8 million in our balance sheet. See 'Item 5. Operating and Financial Review and Prospects - Overview.'

We believe the Company is not exposed to interest rate risk.

ITEM 12. Description of Securities Other Than Equity Securities

ITEM 12.A Debt Securities

Not applicable.

ITEM 12.B Warrants and Rights

Not applicable.

ITEM 12.C Other Securities

Not applicable.

ITEM 12.D American Depositary Shares

Charges of Depositary

The Company will pay fees, reasonable expenses and out-of-pocket charges of the depositary and those of any registrar only in accordance with agreements in writing entered into between the Depositary and the Company from time to time. The following charges shall be incurred by any party depositing or withdrawing shares or by any party surrendering receipts or to whom receipts are issued (including, without limitation, issuance pursuant to a stock dividend or stock split declared by the Company or an exchange of stock regarding the receipts or deposited securities or a distribution of receipts pursuant to the terms of the deposit agreement):

- taxes and other governmental charges
- any applicable registration or transfer fees
- any cable, telex and facsimile transmission charges as provided in the deposit agreement
- any expenses incurred in the conversion of foreign currency
- $5.00 (or less) per 100 ADSs (or portion thereof) for the execution and delivery of Receipts and surrender of receipts
- $0.02 or less per ADS (or portion thereof) for any cash distribution pursuant to the deposit agreement
- $1.50 or less per certificate for a receipt or transfer of a receipt
- A fee equivalent to the fee that would be payable if securities distributed to you had been shares and the shares had been deposited for issuance of ADSs

PART II

ITEM 13. Defaults, Dividend Arrearages and Delinquencies

There has not been any material default with respect to any indebtedness of the Company.

ITEM 14. Material Modifications to the Rights of Security Holders and Use of Proceeds

Not applicable.

ITEM 15. Controls and Procedures

Disclosure Controls and Procedures

The Company's Chief Executive Officer and Principal Financial Officer have evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of December 31, 2012. Based on this evaluation, the Chief Executive Officer and Principal Financial Officer of the Company concluded that the Company's disclosure controls and procedures were effective as of December 31, 2012.

Changes in Internal Control over Financial Reporting

There have been no changes in the Company's internal control over financial reporting that occurred during the Company's fiscal year ended December 31, 2012 that has materially affected, or is reasonable likely to materially affect, the Company's internal control over financial reporting.

Management's Annual Report on Internal Control over Financial Reporting

The management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934) of the Company.

The internal control over financial reporting at the Company was designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. Internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with accounting principles generally accepted in the United States of America;
- provide reasonable assurance that receipts and expenditures of the Company are being made only in accordance with authorization of management and directors of the Company; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of assets that could have a material effect on the consolidated financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with policies or procedures may deteriorate.

The Company's management assessed the effectiveness of the company's internal control over financial reporting as of December 31, 2012. Management based this assessment on criteria for effective internal control over financial reporting described in "Internal Control – Integrated Framework" issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, management determined that, as of December 31, 2012, the Company maintained effective internal control over financial reporting. Management reviewed the results of its assessment with the Audit Committee of the Board of Directors.

Attestation report of registered public accounting firm

The effectiveness of the Company's internal control over financial reporting has been audited by PricewaterhouseCoopers, an independent registered accounting firm, as stated in their report on the Company's internal control over reporting as of December 31, 2012, which is included herein.
See report of PricewaterhouseCoopers, an independent registered accounting firm, included within the financial statements on page F-2.

ITEM 16. [Reserved]

ITEM 16A. Audit Committee Financial Expert

The Board has determined that Elie Vannier and Guillaume Cerutti are 'audit committee financial experts,' as defined by the rules of the SEC. Messrs Vannier and Cerutti are 'independent' as defined by the NASDAQ Marketplace Rules.

ITEM 16B. Code of Ethics

The Board adopted a written Code of Ethics that applies to the Chief Executive Officer, Chief Operating Officer and senior financial officers. The principles set forth in our Code of Ethics are intended to promote the honest and ethical conduct of our principal executive officer, the principal financial officer, the principal accounting officer or controller, or persons performing similar functions. The Code of Ethics was filed as Exhibit 11.1 to our annual report on Form 20-F for the year ended December 31, 2003, on April 26, 2004.

ITEM 16C. Principal Accountant Fees and Services

The following is a summary of the fees billed to Flamel by PricewaterhouseCoopers for professional services rendered for the fiscal years ended December 31, 2012 and 2011:

Fee Category	Fiscal 2012 Fees (Euros)	Fiscal 2011 Fees (Euros)
Audit Fees	297,000	201,900
Audit-Related Fees	7,900	10,400
Tax Fees		-
All Other Fees		-
Total Fees	**304,900**	**212,300**

All fees were billed in Euros. Using the average exchange rate of 1.2856 U.S dollars per Euro for 2012, and 1.39137U.S dollars per Euro for 2011 audit fees equaled $391,979 for Fiscal 2012 and $295,388 for Fiscal 2011.

Audit Fees. Consists of fees billed for professional services rendered for the audit of the Company's consolidated financial statements, review of the interim consolidated financial statements included in quarterly reports and review of internal controls over Financial Reporting.

Audit-Related Fees. Consists of fees billed for assurance and related services by the principal accountant that are reasonably related to the performance of the audit or review of Flamel's consolidated financial statements.

Tax Fees. Consists of fees billed for professional services for tax compliance, tax advice and tax planning.

All Other Fees. There were no fees billed for professional services in fiscal years 2009 and 2008 that are not included in one of the above categories.

Audit Committee's Pre-Approval Policies and Procedures

Our Audit Committee nominates and engages our independent auditors to audit our financial statements. See also 'Item 6. Directors, Senior Management and Employees – Board Practices – Committees of the Board of Directors.' In 2005, our Audit Committee adopted a revised policy requiring management to obtain the Committee's approval before engaging our independent auditors to provide any other audit or permitted non-audit services to us or our subsidiaries. Pursuant to this policy, which is designed to assure that such engagements do not impair the independence of our auditors, the Audit Committee annually pre-approves, in accordance with an audit plan, specific audit and non-audit services in the categories Audit Service, Audit-Related Services, Tax Consulting Services, and Other Services that may be performed by our auditors. All of the fees to the principal accountants were approved by the Audit Committee pursuant to paragraph (c)(7)(i)(C) of Rule 2-01 of Regulation S-X in 2005. Our Principal Financial Officer reviews all individual management requests to engage our auditors as a service provider in accordance with this policy and, if the requested services are permitted pursuant to the audit plan approved by the Audit Committee and are less than €10,000, approves the request accordingly. In the event of a request for services pursuant to the audit plan in excess of €10,000 and less than €20,000, the Chairman of the Audit Committee approves the request. Any services in excess of €20,000 are to be pre-approved by the Audit Committee. We inform the Audit Committee about all approvals made by the Principal Financial Officer or Chairman of the Audit Committee at the following Audit Committee meeting. The chairman of our Audit Committee is not permitted to approve any engagement of our auditors if the services to be performed either fall into a category of services that are not permitted by applicable law or the services would be inconsistent with maintaining the auditors' independence.

ITEM 16D. Exemptions from the Listing Standards for Audit Committees

Not applicable.

ITEM 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers

Not applicable**.**

ITEM 16F. Change in Registrant's Certifying Accountant

Not applicable**.**

ITEM 16G. Corporate Governance

Flamel was incorporated under the laws of France with securities listed on the Nasdaq Global Market, a regulated public market in the U.S. Our corporate governance framework reflects the mandatory provisions of French law and may differ in certain respects described below from the practices followed by U.S. companies listed on the Nasdaq Global Market.

The Company is exempt from NASDAQ's quorum requirements applicable to meetings of shareholders. In keeping with French law and generally accepted business practices in France, the presence in person or by proxy of shareholders having not less than 20% (in case of an ordinary general meeting or an extraordinary general meeting deciding upon any capital increase by capitalization of reserves) or 25% (in the case of an extraordinary general meeting) of the Shares is necessary for a quorum. If a quorum is not present at any meeting, the meeting is adjourned. Upon recommencement of an adjourned meeting, there is no quorum requirement in the case of an ordinary general meeting or an extraordinary general meeting deciding upon any capital increase by capitalization of reserves. The presence in person or by proxy of shareholders having not less than 20% of the Shares is necessary for a quorum in the case of any other type of extraordinary general meeting.

The Company also has been granted an exemption from NASDAQ Marketplace 5620 (b). The French Commercial Code does not require that we solicit or provide proxy statements for meetings of shareholders. In accordance with the French Commercial Code and our *statuts*, we inform shareholders of all meetings in a public notice, which notice states the requirements for admission to the meeting. Meeting the Nasdaq requirement to solicit proxies and provide proxy statements for shareholder meetings would be contrary to accepted business practice in France.

French corporate law provides that the Board of Directors must vote to authorize certain related party transactions that could create conflicts of interest between Flamel on the one hand and its directors, chief executive officer or shareholders owning more than 10% of the voting rights on the other hand for such transactions to be legally binding and must have such transactions documented, audited and approved by the shareholders at each ordinary shareholders' meeting approving the annual French statutory accounts of the Company. If the shareholders do not approve such related party transactions, the transactions remain legally binding, provided that they are not fraudulent and consequently declared null and void by competent courts.

Under French law, the committees of our Board of Directors are advisory only, and where the Nasdaq requirements would vest certain decision-making powers with specific committees by delegation (e.g., nominating or audit committees), our Board of Directors remains under French law the only competent body to take such decisions, albeit taking into account the recommendation of the relevant committees. Additionally, under French corporate law, it is the shareholder meeting of the Company that is competent to appoint our auditors upon the proposal of our Board of Directors.

In addition to the oversight role of our Compensation Committee for questions of management compensation including by way of equity, under French law any option plans or other share capital increases, whether for the benefit of top management or employees, may only be adopted by the Board of Directors pursuant to and within the limits of a shareholder resolution approving the related capital increase and delegating to the Board the authority to implement such operations.

As a 'foreign private issuer' under the U.S. securities laws, our Chief Executive Officer and our Principal Financial Officer issue the certifications required by §302 and §906 of the Sarbanes Oxley Act of 2002 on an annual basis (with the filing of our annual report on Form 20-F) rather than on a quarterly basis as would be the case of a U.S. corporation filing quarterly reports on Form 10-Q.

ITEM 16H. Mine Safety Disclosure

Not applicable

PART III

ITEM 17. Financial Statements

Not applicable. See 'Item 18. Financial Statements.'

ITEM 18. Financial Statements

The following financial statements, together with the reports of Independent registered accounting firm thereon, are filed as part of this Annual Report:

See pages F-1 through F-38 incorporated herein by reference

The registrant undertakes to provide to each shareholder requesting the same a copy of each exhibit referred to herein upon payment of a reasonable fee limited to the registrant's reasonable expenses in furnishing such exhibit.

ITEM 19. Exhibits

EXHIBIT INDEX

Exhibit Number	Description
1.1	Revised *Statuts* or bylaws of the Company (Filed herewith)
2.1	Deposit Agreement among Flamel, The Bank of New York, as Depositary, and holders from time to time of American Depositary Shares issued thereunder (including as an exhibit the form of American Depositary Receipt) (1)
4.1*	Note Agreement among Flamel Technologies S.A., Flamel US Holdings, Inc. and Éclat Holdings, LLC, dated March 13, 2012 (2)
4.2	Guaranty of Note made by Flamel Technologies S.A. in favor of Éclat Holdings, LLC, dated March 13, 2012 (2)
4.3	Warrant to purchase 2,200,000 American Depositary Shares, each representing one Ordinary Share of Flamel Technologies S.A. (2)
4.4	Warrant to purchase 1,100,000 American Depositary Shares, each representing one Ordinary Share of Flamel Technologies S.A. (2)
4.5	Registration Rights Agreement between Flamel Technologies S.A. and Éclat Holdings, LLC, dated March 13, 2012 (2)
4.6	Registration Statement on form F-3 filed on September 18, 2012 (4)
4.7	Facility Agreement among Flamel US Holdings, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P dated December 31, 2012 (Filed herewith)
4.8*	Royalty Agreement among Eclat Pharmaceuticals LLC, Horizon Santé FLML, Sarl and Deerfield Private Design Fund II, L.P dated December 31, 2012 (Filed herewith)
4.9*	Security Agreement between Éclat Pharamaceuticals, LLC and Deerfield Private Design Fund II, L.P. and Horizon Santé FLML, Sarl, dated February 4, 2013 (Filed herewith)
8.1	List of Subsidiaries (Filed herewith)
11.1	Code of Ethics for CEO (*Directeur Généra*l), Delegated Managing Directors (*Directeurs Généraux Délégués*) and Senior Financial Officers (3)
12.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Filed herewith)

12.2	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Filed herewith)
13.1	Certification of the Chief Executive Officer pursuant to USC Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Furnished herewith)
13.2	Certification of the Principal Financial Officer pursuant to USC Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Furnished herewith)
23.1	Consent of PricewaterhouseCoopers Audit (Filed herewith)

(1) Incorporated by reference to Post-Effective Amendment No. 1 to the Company's registration statement on Form F-6 filed July 26, 2001, as amended (No. 333-12790).
(2) Incorporated by reference to the Company's Current Report on Form 6-K, filed March 21, 2012.
(3) Incorporated by reference to the Company's Annual Report on Form 20-F for the year ended December 31, 2003, filed on April 26, 2004.
(4) Incorporated by reference to the Company's registration statement on Form F-3, filed September 18, 2012 (No. 333-183961).

*Confidential treatment has been requested for the redacted portions of this agreement. A complete copy of the agreement, including the redacted portions, has been filed separately with the Securities and Exchange Commission.

FLAMEL TECHNOLOGIES S.A.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders,
Flamel Technologies SA
Vénissieux

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, of comprehensive income, of shareholders' equity and of cash flows present fairly, in all material respects, the financial position of Flamel Technologies SA and its subsidiaries at December 31, 2012 and 2011, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2012 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control over Financial Reporting, appearing on page 81 of the 2012 Annual Report to Shareholders. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Lyon, France, April 30, 2013

PricewaterhouseCoopers Audit

/s/ Bernard Rascle
Bernard Rascle (signed)

FLAMEL TECHNOLOGIES S.A.

CONSOLIDATED BALANCE SHEETS
(Amounts in thousands of dollars except share data)

	Note	December 31, 2011	December 31, 2012
ASSETS			
Current assets:			
Cash and cash equivalents	7	$ 3,456	$ 2,742
Marketable securities	8	21,035	6,413
Accounts receivable (net of allowance of $137 and $139 at December 31, 2011 and 2012 respectively)		7,765	5,464
Note receivable	16	-	-
Inventory	9	1,675	1,520
Research and development tax credit receivable current portion	20	79	6,632
Prepaid expenses and other current assets	10	2,642	2,314
Total current assets		36,652	25,085
Goodwill	12	-	18,491
Property and equipment, net	11	19,383	18,238
Intangible assets, net	12	-	41,589
Other assets:			
Research and development tax credit receivable less current portion	20	13,203	13,725
Other long-term assets		164	183
Total assets		$ 69,402	$ 117,311
LIABILITIES AND SHAREHOLDERS' EQUITY			
Current liabilities:			
Current portion of long-term debt	16	2,026	3,351
Current portion of capital lease obligations	17	97	77
Accounts payable		3,920	3,596
Current portion of deferred revenue	15	2,836	614
Advances from customers		1,962	575
Accrued expenses	13	5,478	5,013
Other current liabilities	14	1,995	1,133
Total current liabilities		18,314	14,359
Long-term debt, less current portion	16	1,689	33,278
Capital lease obligations, less current portion	17	251	179
Deferred revenue, less current portion	15	1,531	181
Deferred tax liabilities	20	-	14,130
Other long-term liabilities	14 - 21	17,823	24,680
Total long-term liabilities		21,294	72,448
Commitments and contingencies:		-	-
Shareholders' equity :	19		
Ordinary shares: 24,962,250 issued and outstanding at December 31, 2011 and 25,415,400 at December 31, 2012 (shares authorised 33,931,990) at nominal value of 0.122 euro		3,641	3,714
Additional paid-in capital		205,489	209,158
Accumulated deficit		(189,393)	(192,621)
Accumulated other comprehensive income		10,057	10,253
Total shareholders' equity		29,794	30,504
Total liabilities and shareholders' equity		$ 69,402	$ 117,311

FLAMEL TECHNOLOGIES S.A.

CONSOLIDATED STATEMENTS OF OPERATIONS
(Amounts in thousands of dollars except share data)

	Note	Year ended December 31, 2010	2011	2012
Revenue:				
License and research revenue	4	$ 19,704	$ 10,566	$ 9,324
Product sales and services	3	8,180	13,395	9,657
Other revenues		9,210	8,639	7,120
Total revenue		37,094	32,600	26,101
Costs and expenses:				
Cost of products and services sold		(6,914)	(6,284)	(5,860)
Research and development	5	(28,687)	(25,089)	(26,115)
Selling, general and administrative		(11,333)	(10,810)	(14,153)
Remeasurement of acquisition liabilities	2	-	-	18,834
Impairment of assets	2	-	-	(7,170)
Total		(46,934)	(42,183)	(34,464)
Income (loss) from operations		(9,840)	(9,583)	(8,363)
Interest expense		(24)	(73)	(118)
Interest income		464	667	629
Foreign exchange gain (loss)		109	273	(180)
Other income		525	134	102
Income (loss) before income taxes		(8,766)	(8,582)	(7,930)
Income tax	20	(209)	(192)	4,702
Net income (loss)		$ (8,975)	$ (8,774)	$ (3,228)
Earnings (loss) per share				
Basic earnings (loss) per share	18	$ (0.37)	$ (0.36)	$ (0.13)
Diluted earnings (loss) per share		$ (0.37)	$ (0.36)	$ (0.13)
Weighted average number of shares outstanding (in thousands) :				
Basic		24,411	24,669	25,135
Diluted		24,411	24,669	25,135

FLAMEL TECHNOLOGIES S.A.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(Amounts in thousands of dollars except share data)

	Year Ended December 31,		
	2010	**2011**	**2012**
		(In thousands)	
Net loss	$ (8,975)	$ (8,774)	$ (3,228)
Other comprehensive income (loss):			
Net foreign currency translation gain (loss)	(3,596)	(816)	196
Other comprehensive income (loss), net of tax	(3,596)	(816)	196
Comprehensive loss	$ (12,571)	$ (9,590)	$ (3,032)

FLAMEL TECHNOLOGIES S.A.

CONSOLIDATED STATEMENTS OF SHAREHOLDERS EQUITY
(Amounts in thousands of dollars except share data)

	Ordinary Shares		Additional Paid-in	Accumulated	Accumulated Other Comprehensive Income	Shareholders'
	Shares	Amount	Capital	Deficit	(Loss)	Equity
Balance at January 1, 2010	24,342,600	$ 3,540	$ 198,498	$ (171,644)	$ 14,469	$ 44,863
Subscription of warrants			224			224
Issuance of ordinary shares on exercise of stock -options	63,000	11	470			481
Issuance of ordinary shares on vesting of free shares	240,050	38	(38)			-
Stock-based compensation expense			3,308			3,308
Net loss				(8,975)		(8,975)
Other comprehensive income (loss)					(3,596)	(3,596)
Balance at December 31, 2010	24,645,650	$ 3,589	$ 202,462	$ (180,619)	$ 10,873	$ 36,305
Subscription of warrants			200			200
Issuance of ordinary shares on exercise of stock -options	44,200	8	88			96
Issuance of ordinary shares on vesting of free shares	272,400	44	(44)			-
Stock-based compensation expense			2,783			2,783
Net loss				(8,774)		(8,774)
Other comprehensive income (loss)					(816)	(816)
Balance at December 31, 2011	24,962,250	$ 3,641	$ 205,489	$ (189,393)	$ 10,057	$ 29,794
Subscription of warrants			5			5
Issuance of ordinary shares on exercise of stock -options	195,000	31	570			601
Issuance of ordinary shares on vesting of free shares	258,150	42	(42)			-
Stock-based compensation expense			3,136			3,136
Net loss				(3,228)		(3,228)
Other comprehensive income (loss)					196	196
Balance at December 31, 2012	25,415,400	$ 3,714	$ 209,158	$ (192,621)	$ 10,253	$ 30,504

FLAMEL TECHNOLOGIES S.A.

CONSOLIDATED STATEMENTS OF CASH FLOWS
(Amounts in thousands of dollars except share data)

	Year ended December 31,		
	2010	**2011**	**2012**
Cash flows from operating activities:			
Net income (loss)	$ (8,975)	$ (8,774)	$ (3,228)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation of property and equipment	4,696	3,346	3,183
Loss (gain) on disposal of property and equipment	(68)	(11)	(37)
Gains on sales of marketable securities	(74)	(41)	(6)
Grants recognized in other income and income from operations	(884)	(3,227)	(975)
Remeasurement of acquisition liabilities	-	-	(18,834)
Impairment of assets	-	-	7,170
Change in deferred tax	-	-	(4,758)
Stock compensation expense	3,170	2,779	3,040
Increase (decrease) in cash from:			
Accounts receivable	733	(464)	2,610
Inventory	152	(917)	176
Prepaid expenses and other current assets	964	856	800
Research and development tax credit receivable ..	837	(3,938)	(6,642)
Accounts payable	(450)	(825)	(613)
Deferred revenue	(3,358)	856	(4,984)
Accrued expenses	(723)	(491)	(742)
Other current liabilities	(814)	399	(682)
Other long-term assets and liabilities	(663)	129	1,383
Net cash used in operating activities	(5,457)	(10,323)	(23,139)
Cash flows from investing activities:			
Purchases of property and equipment	(3,599)	(1,903)	(1,069)
Proceeds from disposal of property and equipment	131	185	67
Proceeds from sales of marketable securities	83,128	26,382	18,246
Purchase of marketable securities	(73,632)	(25,015)	(3,567)
Cash transferred on acquisition	-		1,771
Net cash provided by (used in) investing activities .	6,028	(351)	15,448
Cash flows from financing activities:			
Reimbursment of loans or conditional grants	(1,879)	(1,910)	(223)
Proceeds from loans or conditional grants	436	7,855	6,668
Principal payments on capital lease obligations	(35)	(96)	(97)
Cash proceeds from issuance of ordinary shares and warrants	704	296	607
Net cash provided by financing activities	(774)	6,145	6,955
Effect of exchange rate changes on cash and cash equivalents	(329)	(199)	22
Net increase (decrease) in cash and cash equivalents	(532)	(4,728)	(714)
Cash and cash equivalents, beginning of year .	8,716	8,184	3,456
Cash and cash equivalents, end of year	$ 8,184	$ 3,456	$ 2,742
Supplemental disclosures of cash flow information:			
Income tax paid	-	-	56
Interest paid	24	73	118
The supplemental schedule of non cash investing and financing activities is as follows			
Capital lease obligations incurred	131	220	-
Fair value of assets acquired at acquisition date:	-	-	50,927
Liabilities assumed at acquisition date:	-	-	50,927

FLAMEL TECHNOLOGIES S.A.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of business and summary of significant accounting policies:

1.1. Nature of business:

Flamel Technologies, S.A. (the "Company") is organized as a *société anonyme*, a form of corporation under the laws of The Republic of France. The Company was founded in 1990. The Company is a specialty pharmaceutical company with a long history of drug delivery expertise. The Company operates primarily in France and has commercial and marketing capabilities in the US.

1.2. Management estimates

The accompanying consolidated financial statements were prepared in accordance with U.S. generally accepted accounting principles (U.S. GAAP).

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates reflected in the consolidated financial statements include, but are not limited to, purchase price allocation of its acquisitions, remeasurement of liabilities accounted at fair value, the recoverability of the carrying amount and estimated useful lives of long-lived assets, in progress R&D and goodwill, share-based compensation expenses, evaluation of long term personnel compensation, calculation of R&D tax credit, and valuation allowance of deferred tax assets. Management makes these estimates using the best information available at the time the estimates are made; however, actual results could differ from those estimates.

1.3. Going concern

Since its inception, the Company has incurred significant net losses resulting in an accumulated deficit of $193 million as of December 31, 2012, which raises substantial doubt about its ability to continue as a going concern. Management believes that the $15 million received in February 2013 from the Facility and Royalty Agreements, as discussed in note 26, and its current working capital as of December 31, 2012 will be sufficient for the company to continue as a going concern for at least the next twelve months.

1.4. Principles of consolidation

The accompanying consolidated financial statements include the Company and its wholly-owned subsidiaries in the United States. All inter-company accounts and transactions have been eliminated. The list of the subsidiaries is detailed in exhibit 8.1

1.5. Translation of financial statements of foreign entities and foreign currency transactions:

The reporting currency of the Company and its wholly-owned subsidiary is the U.S. dollar as permitted by the SEC for a foreign private issuer (S-X Rule 3-20(a)). All assets and liabilities in the balance sheets of the Company, whose functional currency is the Euro, except those of the U.S. subsidiaries whose functional currency is the U.S. dollar, are translated into U.S. dollar equivalents at exchange rates as follows: (1) asset and liability accounts at year-end rates, (2) income statement accounts at weighted average exchange rates for the year, and (3) shareholders' equity accounts at historical rates. Corresponding translation gains or losses are recorded in shareholders' equity.

Transaction gains and losses are reflected in the statement of operations.

The Company has not undertaken hedging transactions to cover its currency translation exposure.

1.6. Revenue recognition:

Revenue includes upfront licensing fees, milestone payments for R&D achievements, compensation for the execution of research and development activities.

Before January 1, 2011, we evaluated arrangements with multiple elements in accordance with Accounting Standards Codification, or ASC, 605-25 Revenue Recognition – Multiple-Element Arrangements. In October 2009, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2009-13 Revenue Arrangements with Multiple Deliverables, or ASU 2009-13, which amended the accounting standards for certain multiple element revenue arrangements to:

- provide updated guidance on whether multiple elements exist, how the elements in an arrangement should be separated, and how the arrangement consideration should be allocated to the separate elements;
- require an entity to allocate arrangement consideration to each element based on a selling price hierarchy, also called the relative selling price method, where the selling price for an element is based on vendor-specific objective evidence ("VSOE"), if available; third-party evidence ("TPE"), if available and VSOE is not available; or the best estimate of selling price ("BESP"), if neither VSOE nor TPE is available; and
- eliminate the use of the residual method and require an entity to allocate arrangement consideration using the selling price hierarchy.

The revenue allocated to each element is then recognized when the basic revenue recognition criteria are met for that element.

On January 1, 2011, we adopted ASU 2009-13 on a prospective basis. The adoption of this new guidance did not have any material impact on our consolidated financial statements.

Where agreements have more than one deliverable, a determination is made as to whether the license and R&D elements should be recognized separately or combined into a single unit of account in accordance with ASU 2009-13, Revenue with Multiple Deliverables.

The Company uses a multiple attribution model, referred to as the milestone-based method:

- As milestones relate to discrete development steps (i.e. can be used by the co-development partners to decide whether to continue the development under the agreement), the Company views that milestone events have substance and represent the achievement of defined goals worthy of the payments. Therefore, milestone payments based on performance are recognized when the performance criteria are met and there are no further performance obligations.
- Non-refundable technology access fees received from collaboration agreements that require the Company's continuing involvement in the form of development efforts are recognized as revenue ratably over the development period.
- Research and development work is compensated at a non-refundable hourly rate for a projected number of hours. Revenue on such agreements is recognized proportionally to the actual number of hours worked compared to the latest estimated total hours.. Costs incurred under these contracts are considered costs in the period incurred. Payments received in advance of performance are recorded as deferred revenue and recognized in revenue as services are rendered.

The Company recognizes revenue from product sales when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed and determinable, and collectibility is reasonably assured.

The Company receives royalty revenues under a license agreement with a third party that sells products based on technology developed by the Company. There are no future performance obligations on the part of the Company under this license agreement. The license agreements provide for the payment of royalties to the Company based on sales of the licensed product. The Company records these revenues based on actual sales that occurred during the relevant period and classified these revenues in 'Other Revenues'.

The Company signs feasibility study agreements. Revenue is recognized over the term of the agreement as services are performed.

1.7. Governmental Grants:

The Company receives financial support for various research or investment projects from governmental agencies.

The Company recognizes conditional grants related to specific development projects conditioned on completion of investment program and ongoing employment at the facilities as an offset to operating expenses once all conditions stated in the grant have been met.

The Company recognizes unconditional grants for research and development (R&D) projects requiring the collaboration of both private and public research partners as an offset to R&D expense on a pro-rata basis over the duration of the program.

The Company receives funds to finance R&D projects. These funds are repayable on commercial success of the project. In the absence of commercial success, the Company is released of its obligation to repay the funds and as such the funds are recognized in the Income Statement as 'Other Income'. The absence of commercial success must be formally confirmed by the granting authority. Should the Company wish to discontinue the research and development to which the funding is associated, the granting authorities must be informed.

1.8. Research and development costs:

Research and development (R&D) expenses comprise the following types of costs incurred in performing R&D activities: salaries, allocated overhead and occupancy costs, clinical trial and related clinical manufacturing costs, contract and other outside service fees. Research and development expenditures are charged to operations as incurred.

The Company does not disclose research development costs per partner funded contract and does not believe such disclosure would be material to investors.

1.9. Concentration of credit risk:

The Company's cash and cash equivalents are deposited with HSBC, Crédit Agricole, Commerce Bank and Citibank.

The marketable securities issued by Credit Agricole have strong credit ratings (rated "A" by Standard and Poor)

The Company's revenues are derived mainly from collaborative research and development contracts and supply agreements with pharmaceutical companies based in Europe and the United States. All significant customers are discussed in Note 4.

The Company performs ongoing credit evaluations of its customers and maintains provisions for potential credit losses as considered necessary. The Company generally does not require collateral. Historically, the Company has not experienced significant credit losses on its customer accounts. The allowance for doubtful accounts was $141,000, $137,000 and $139,000 at December 31, 2010, 2011 and 2012, respectively.

1.10. Earnings per share:

Basic earnings (loss) per share is computed by dividing net income (loss) by the weighted average number of shares of common stock outstanding for the period. Diluted earnings per share reflects potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock that then shared in the earnings of the Company. The dilutive effects of the Company's common stock options and warrants is determined using the treasury stock method to measure the number of shares that are assumed to have been repurchased using the average market price during the period, which is converted from U.S. dollars at the average exchange rate for the period. Such securities are not considered in computing diluted loss per share as their effects would be anti-dilutive.

1.11. Cash and cash equivalents:

Cash and cash equivalents consist of cash on hand, cash on deposit and fixed term deposit being highly liquid investments with a maturity of three months or less at the date of purchase.

1.12. Marketable securities:

Marketable securities consist of highly liquid investments in money market mutual funds. Marketable securities are classified as available-for-sale securities in accordance with ASC 320-10, "Accounting for Certain Investments in Debt and Equity Securities" These investments are recorded at fair value, which is based on quoted market prices. Accordingly, unrealized gains and losses are included in accumulated other comprehensive income until realized.

1.13. Accounts Receivable:

Accounts receivable are stated at amounts invoiced net of allowances for doubtful accounts**.** The Company makes judgments as to its ability to collect outstanding receivables and provides allowances for the portion of receivables deemed uncollectible. Provision is made based upon a specific review of all significant outstanding invoices.

1.14. Inventories:

Inventories consist of raw materials and finished products, which are stated at cost determined under the first-in, first-out ("FIFO") method. Raw materials used in the production of pre-clinical and clinical products are expensed as research and development costs when consumed. The Company establishes reserves for inventory estimated to be obsolete, unmarketable or slow-moving on a case by case basis.

1.15. Property and equipment:

Property and equipment is stated at historical cost less accumulated depreciation. Depreciation and amortization are computed using the straight-line method over the following estimated useful lives:

Land and buildings	20 years
Laboratory equipment	4 - 8 years
Office and computer equipment	3 years
Furniture, fixtures and fittings	5-10 years

Assets under capital leases are amortized over the economic lives of the assets. Amortization of the carrying value of assets under capital leases is included in depreciation expense.

1.16. Goodwill and intangible assets

Goodwill represents the excess of purchase price over the fair value of identifiable net assets of businesses acquired. Goodwill is not amortized, but instead tested annually for impairment or more frequently when events or change in circumstances indicate that the assets might be impaired by comparing the carrying value to the fair value of the reporting units to which it is assigned. Under ASC 350, “Goodwill and other intangible assets”, the impairment test is performed in two steps. The first step compares the fair value of the reporting unit with its carrying amount, including goodwill. If the fair value of the reporting unit is less than its carrying amount, a second step is performed to measure the amount of impairment loss. The second step allocates the fair value of the reporting unit to the Company’s tangible and intangible assets and liabilities. This derives an implied fair value for the reporting unit’s goodwill. If the carrying amount of the reporting units goodwill exceeds the implied fair value of that goodwill, an impairment loss is recognized equal to that excess. For the purpose of any impairment test, the Company relies upon projections of future undiscounted cash flows and takes into account assumptions regarding the evolution of the market and its ability to successfully develop and commercialize its products.

Changes in market conditions could have a major impact on the valuation of these assets and could result in additional impairment losses.

Intangible assets consist primarily of purchased licenses and in progress R&D recognized as part of the Eclat acquisition purchase price allocation. Acquired IPR&D has an indefinite life and is not amortized until completion and development of the project, at which time the IPR&D becomes an amortizable asset. If the related project is not completed in a timely manner or the project is terminated or abandoned, we may have an impairment related to the IPR&D, calculated as the excess of the asset’s carrying value over its fair value.

Our policy defines IPR&D as the value assigned to those projects for which the related products have not received regulatory approval and have no alternative future use. Determining the portion of the purchase price allocated to IPR&D requires us to make significant estimates. The amount of the purchase price allocated to IPR&D is determined by estimating the future cash flows of each project or technology and discounting the net cash flows back to their present values. The discount rate used is determined at the time of measurement in accordance with accepted valuation methods. These methodologies include consideration of the risk of the project not achieving commercial feasibility.

At the time of acquisition, we expect that all acquired IPR&D will reach technological feasibility, but there can be no assurance that the commercial viability of these products will actually be achieved. The risks associated with achieving commercialization include, but are not limited to, delay or failure to obtain required market clearances.

1.17. Impairment of Long-Lived Assets:

The Company reviews the carrying value of its long-lived assets, including fixed assets and intangible assets, for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be fully recoverable. Recoverability of long-lived assets is assessed by a comparison of the carrying amount of the asset (or the group of assets, including the asset in question, that represents the lowest level of separately-identifiable cash flows) to the total estimated undiscounted future cash flows expected to be generated by the asset or group of assets. If the future net undiscounted cash flows is less than the carrying amount of the asset or group of assets, the asset or group of assets is considered impaired and an expense is recognized equal to the amount required to reduce the carrying amount of the asset or group of assets to its then fair value. Fair value is determined by discounting the cash flows expected to be generated by the asset, when the quoted market prices are not available for the long-lived assets. Estimated future cash flows are based on management assumptions and are subject to risk and uncertainty.

1.18. Income taxes:

The Company accounts for income taxes in accordance with ASC 740. Under ASC 740, deferred tax assets are determined based on the difference between the financial reporting and tax basis of assets and liabilities, applying enacted statutory tax rates in effect for the year in which the tax differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. Deferred tax assets and liabilities are adjusted for the effects of changes in the tax laws and rates on the date of enactment.

1.19. Research credit tax

The Company is eligible to receive a French research tax credit that is calculated based on a percentage of eligible research and development costs. The tax credit can be refundable in cash and is not contingent on future taxable income. As such, the Company considers the research credit tax as a grant, offsetting operating expenses.

1.20. Employee stock options and warrants:

The Company accounts for Stock based compensation based on grant-date fair value estimated in accordance with ASC 718.

The Company estimated the fair value of stock options and warrants using a Black-Scholes option-pricing valuation model (“Black-Scholes model”).

The Company uses a simplified method to estimate the maturity. The Company considered historical data was insufficient and irrelevant relative to the grant of stock-options and warrants to a limited population and the simplified method was used to determine the expected term for stock-options and warrants granted.

The Company recognizes compensation cost, net of an estimated forfeiture rate, using the accelerated method over the requisite service period of the award.

1.21. Recent Accounting Pronouncements

In July 2012, the FASB issued ASU 2012-02, “Testing Indefinite-Lived Intangible Assets for Impairment” (“ASU 2012-02”). ASU 2012-02 allows a company to first assess qualitative factors to determine whether it is more-likely-than-not that an indefinite-lived intangible asset is impaired. The more likely-than-not threshold is defined as having a likelihood of more than 50 percent. If based on its qualitative assessment, a company concludes that it is more likely than not that the fair value of an indefinite-lived intangible asset is less than its carrying amount, then quantitative impairment testing is required. However, if a company concludes otherwise, quantitative impairment testing is not required. ASU 2012-02 is effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012 with early adoption permitted. The adoption of ASU 2012- 02 will not affect the consolidated financial position, results of operations or cash flows of the Company.

In September 2011, the FASB issued ASU 2011-08, “Testing Goodwill for Impairment” (“ASU 2011-08”). ASU 2011-08 allows a company to first assess qualitative factors to determine whether it is more-likely-than-not that the fair value of a reporting unit is less than its carrying amount as a basis for determining whether it is necessary to perform the two-step goodwill impairment test. The more-likely-than-not threshold is defined as having a likelihood of more than 50 percent. The provisions of ASU 2011-08 are effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011 with early adoption permitted. The adoption of ASU 2011-08, did not impact on the consolidated financial position, results of operations or cash flows of the Company.

In June 2011, the FASB issued ASU 2011-05, “Presentation of Comprehensive Income” (“ASU 2011-05”). ASU 2011-05 requires, in part, that companies present the total of comprehensive income, the components of net income and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. The provisions of ASU 2011-05 are effective for fiscal years,and interim periods within those years, beginning after December 15, 2011. The adoption of ASU 2011-05, did not impact on the consolidated financial position, results of operations or cash flows of the Company.

In June 2011, the FASB issued ASU 2011-04, “Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs (ASU 2011-04).” ASU 2011-04 requires expansion of the disclosures required for Level 3 measurements of fair value and provides updates to the existing measurement guidance. The provisions of ASU 2011-04 are effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. The adoption of ASU 2011-04, did not impact on the consolidated financial position, results of operations or cash flows of the Company

2. Business combinations

Effective March 13, 2012, Flamel acquired, through its wholly owned subsidiary Flamel US Holdings, Inc., or Flamel US, all of the membership interests of Éclat Pharmaceuticals, LLC, or Éclat Pharmaceuticals, from Éclat Holdings, LLC, or Éclat Holdings, an affiliate of Flamel’s largest shareholder Deerfield Capital L.P. Éclat Pharmaceuticals is a specialty pharmaceuticals business focused on the development, approval and commercialization of niche brands and generic pharmaceutical products. In exchange for all of the issued and outstanding membership interests of Éclat Pharmaceuticals, Flamel US provided consideration consisting of:

- a $12 million senior, secured six-year note that is guaranteed by the Company and its subsidiaries and secured by the equity interests and assets of Éclat;
- two warrants to purchase a total of 3,300,000 American Depositary Shares, each representing one ordinary share of Flamel (“ADSs”); and
- a commitment to make earn out payments of 20% of any gross profit generated by certain Éclat Pharmaceuticals launch products
- a commitment to pay 100% of any gross profit generated by Hycet® up to a maximum of $1 million.

The Purchase Agreement also contains certain representations and warranties, covenants, indemnification and other customary provisions.

Flamel US issued the note pursuant to a Note Agreement among Flamel, Flamel US and Éclat Holdings dated March 13, 2012. The note is payable over six years only if certain contingencies are satisfied, namely that: (a) two or more Éclat Pharmaceuticals launch products are approved by the FDA, or (b) one Éclat Pharmaceuticals launch product is approved by the FDA and has generated $40 million or more in cumulative net sales. These contingencies are referred to as thresholds. If either Threshold is satisfied, Flamel US will pay 25% of the original principal amount due under the note on each of the third, fourth, fifth and sixth anniversaries of the date of the note. The note accrues interest at an annual rate of 7.5% (calculated on the basis of the actual number of days elapsed in each month) and is payable quarterly in arrears commencing on July 2, 2012 and on the first business day of each October, January, April and July thereafter; provided, however, that if on any such interest payment date, at least one Éclat Pharmaceuticals launch product has not been approved by the FDA, the interest payable on such date will not be payable, but will be added on such date to the outstanding principal amount of the note. Flamel must pay any interest so accrued no later than nine months after such FDA approval and, upon such payment; such outstanding principal amount of the note will be reduced by the amount thereof.

In addition to the note, two six year warrants were issued to purchase an aggregate of 3,300,000 ADSs, each representing one ordinary share, of Flamel. One warrant is exercisable for 2,200,000 ADSs at an exercise price of $7.44 per ADS, and the other warrant is exercisable for 1,100,000 ADSs at an exercise price of $11.00 per ADS. The warrants provide that they may only be exercised for six years following the approval, for the purposes of French law, by the holders of a majority of Flamel's ordinary shares, of the authorization and issuance of the warrants and the ordinary shares underlying the warrants and the waiver of all preferential subscription rights of holders of ordinary shares (and ADSs) with respect to the warrant and the underlying shares. On June 22, 2012, the authorization and issuance and waiver were approved by the holders of the requisite number of ordinary shares

The acquisition-date fair value of the consideration transferred totaled $50,927,000 which consisted of the following:

(Amounts in thousands of USD)

Note	$	5,625
Warrants		12,065
Deferred consideration		33,237
Total acquisition liabilities	$	50,927

The fair value of the note was estimated using a probability-weighted discounted cash flow model. This fair value measurement is based on significant inputs not observable in the market and thus represents a level 3 measurement as defined in ASC 820. The key assumptions are as follows: 20% discount rate, 72% probability of success.

The fair value of the warrants was determined by using a Black-Scholes option pricing model with the following assumptions:

Share price	$	7.29
Risk-free interest rate		2.00%
Dividend yield		-
Expected volatility		56.26%
Expected term		6.0 years

The deferred consideration fair value was estimated by using a discounted cash flow model based on probability adjusted annual gross profit of each of the Éclat Pharmaceuticals products. A discount rate of 20% has been used, except for Hycet for which a discount rate of 13% has been retained.

The transaction was accounted for as a business combination under the acquisition method of accounting. Accordingly, the tangible assets and identifiable intangible assets acquired and liabilities assumed were recorded at fair value, with the remaining purchase price recorded as goodwill.

The following table summarizes the final fair values of the assets acquired and liabilities assumed at the acquisition date.

At March 13, 2012
(Amounts in thousands of USD)

Cash and cash equivalent	$	1,771
Account receivables		210
Inventories		38
Prepaid expenses and other current assets		430
Property and equipment, net		57
Intangible assets		49,282
Goodwill		18,491
Total identifiable assets acquired		70,279
Current liabilities		(459)
Deferred Tax Liabilities		(18,887)
Long term liabilities		(6)
Total liabilities assumed		(19,352)
Net identifiable assets acquired	$	70,279
Net assets acquired	$	50,927

Of the $49,282,000 of acquired intangible assets, $47,309,000 was allocated to in-process research and development (IPR&D) assets that were recognized at fair value on the acquisition date. The fair value was determined using an income approach, including a discount rate of 20%, applied to probability adjusted after-tax cash flows. The estimated costs to complete the IPR&D projects represents management's best estimate of expected costs, but are subject to change based on additional information received as development activities advance. The remaining useful life has been estimated to be four years once the products in question have been approved. The remaining $1,973,000 was allocated to the acquired product license for Hycet® (3-year useful economic life).

The deferred tax liability of $18.9 million relates to temporary differences associated primarily with the IPR&D, which are not deductible for tax purposes. Deferred taxes have been calculated at the statutory rate of 40%.

The difference between the purchase price and the fair value of the assets acquired and liabilities assumed of $18.5 million was allocated to goodwill. This goodwill is attributable to the remaining product opportunities identified by the acquired entity at the date of acquisition, but for which limited development had occurred and the regulatory approval process had not commenced. None of the goodwill is expected to be deductible for income tax purposes.

The Company recognized $635,000 of acquisition related costs that were expensed and included in SG&A expenses.

The amounts of revenues and earnings of Éclat Pharmaceuticals included in the Company's consolidated income statement from the acquisition date to the period ending December 31, 2012 (in thousands) are as follows:

		Revenue and earnings included in the consolidated income statement from March 13, 2012 to December 31, 2012
Revenues	$	560
Net Income/(Loss)	$	(5,301)

The following supplemental pro forma information presents Flamel's financial results for the twelve month period as if the acquisition of Éclat Pharmaceuticals had occurred on January 1, 2011 (in thousands):

		Twelve months ended December 31,	
		2011	2012
		(unaudited)	
Revenues		$ 33,209	$ 26,314
Net Income/(Loss)	(a)	$ (13,624)	$ (3,754)

The above unaudited pro forma information was determined based on the historical US GAAP results of Flamel and Éclat Pharmaceuticals. The unaudited pro forma consolidated results are not necessarily indicative of what the Company's consolidated results of operations actually would have been if the acquisition was completed on January 1, 2011. The unaudited pro forma consolidated net income primarily reflects adjustment of:

i. Elimination of $0.6 million of transaction costs, which are directly attributable to the transaction, for Flamel for the period ended December 31, 2012, and integration of these costs as if they were expensed in the period ended December 31, 2011.
ii. Adjustment to record the estimated amortization expense for intangible asset. The amortization expense was calculated using estimated useful life of three years for the Hycet product license acquired by Éclat Pharmaceuticals in July 2011, with an estimated value of $2.0 million, considering the acquisition would have been completed on January 1, 2011. The amortization for period ended December 31, 2011 amounts to $660,000.
iii. An adjustment to record the estimated increase in amortization expense for intangible assets for the period prior to the acquisition (from January 1, 2012 to March 13, 2012). The incremental expense for the three months was $25,000.

Net loss for the twelve month period ended December 31, 2012 includes income of $14.4 million of which $18.8 million represents remeasurement of the fair value of the acquisition liabilities and $4.3 million of expenses net of tax in connection with the impairment of certain assets acquired. The Company's result of operations in future periods will be affected by the movements in the fair value of the acquisition liabilities which are remeasured at each balance sheet date. Changes in fair value will be recognized in operating income. Changes in assumptions or other variants used to calculate the fair value of acquisition liabilities, such as,but not limited to, the Company's share price, volatility of the share price, discount rates, probability assessment of success in completing development and commercializing acquired products, market share, market size and selling prices negotiated for each product will have an effect on the fair value of the acquisition liabilities. Future non-discounted probability adjusted deferred consideration payments are expected to amount to $49.6 million.

The variation in the fair value of the acquisition liabilities from acquisition date to December 31, 2012, resulting from new facts and circumstances that occurred post acquisition regarding the potential competitive landscape of products in the portfolio, including the abandon of one potential product, is as follows:

		as of December 31, 2012		
(In thousands of U.S. dollars)	Acquisition date fair value	Payments	Remeasurement	Net
Acquisition liability deferred consideration	$ 33,237	$ (160)	$ (9,013)	$ 24,064
Acquisition liability note	5,625	-	87	5,712
Acquisition liability warrant consideration	12,065	-	(9,908)	2,157
Total	$ 50,927	$ (160)	$ (18,834)	$ 31,933

The acquisition liability warrant consideration has been classified as a debt instrument (*see note 16 Long Term Debt*).

As of December 31, 2012, the Company conducted impairment tests of the IPR&D and recognized an expense of $7,170,000, based on the management's best estimates of the present value of future cash flows compiled on a project by project and product by product basis (*see note 12 Goodwill and intangible assets*). The impairment of these assets results from new facts and circumstances that occurred post acquisition regarding the potential competitive landscape of one of the products in the portfolio.

3. Subcontracting agreement:

In accordance with the terms of a supply agreement signed with GSK in December 2004 and renewed in May 2008 for the manufacture of Coreg CR microparticles on a cost plus basis, the Company recognized as revenues from product sales a total amount of $8,180,000 in 2010. This supply agreement expired on December 31, 2010. In October, 2011, the Company announced that it signed a new supply agreement with GSK for the production of Coreg CR microparticles. Under the agreement, the Company is entitled to guaranteed minimum payments to supply Coreg CR microparticles over a period of five years. No earlier than January 1, 2013, GSK may terminate the agreement at their sole discretion by giving six months written notice. Pursuant to the agreement, the Company received a payment of € 1,300,000 ($1,835,000) during the third quarter of 2011 and a further €1,300,000 ($1,752,000) payment in the fourth quarter of 2011, as well as a higher margin on all product produced by Flamel for GSK since January 1, 2011. For the year 2011, the Company recognized as revenues from product sales a total amount of $13,395,000 of which $2,711,000 relates to the €2,600,000 received in the third quarter and the fourth quarter 2011. For 2012, the Company recognized as revenues from product sales a total amount of $9,097,000 of which $852,000 relates to the €2,600,000 received in 2011.

4. License, research and consulting agreements:

GlaxoSmithKline (GSK)

In March 2003, Flamel Technologies and SB Pharma Puerto Rico Inc, an affiliate of GSK entered into a license agreement whereby the Company agreed to license its controlled-release Micropump® in order to develop a new formulation for carvedilol, which is marketed by GSK as Coreg.

In 2010, the Company recognized $8,541,000 of royalties on Coreg sales.

In 2011, the Company recognized $8,210,000 of royalties on Coreg sales.

In 2012, the Company recognized $6,870,000 of royalties on Coreg sales

In December 2004, Flamel and GSK (GSK) entered into a four year supply agreement whereby Flamel agreed to supply GSK with commercial supplies of product. The provisions of the agreement include payments to Flamel of $20,717,000 to support the costs and capital expenditure relative to the creation of a manufacturing area for the production of commercial supply of the product. The capital expenditures consist of both buildings and fixtures, and production equipment. Flamel will have immediate title to buildings and fixtures; however title to production equipment remains with GSK for the duration of the supply agreement.

If the Company breaches the supply agreement through gross negligence, GSK can choose to terminate the supply agreement. The likely occurrence of this event is deemed remote given the Company's ability to perform under supply arrangements based on its historical experience. In the event of a breach and a decision to terminate the agreement, all payments received become repayable to GSK and Flamel will receive immediate title to all production equipment.

Upon cessation of the supply agreement, in the normal course of business, GSK will pass title to all production equipment to Flamel without cost of any kind.

A total of $8,188,000 has been incurred on the acquisition of buildings and fixtures and a total of $11,138,000 has been incurred on behalf of GSK for the purchase of production equipment and associated costs. As of December 31, 2012, the funds received from GSK to finance the acquisition of assets owned by Flamel are classified in other current liabilities for $317,000 and in other long term liabilities for $3,818,000. The liability is amortized on a pro-rata basis over the expected life of the related assets and reflected as an offset of the depreciation of the related assets.

In July 2006, Flamel and GSK entered into a further agreement as a supplement to the original supply agreement whereby GSK partly sponsored the extension of the then existing facilities at Pessac from two lines to three. GSK has exclusive use of part of this equipment, for the production of Coreg CR microparticles. The total funding provided by GSK amounted to $8.1 million to finance the acquisition of equipments, buildings and fixtures. The Company received all installments due under the agreement by December 31, 2007. As of December 31, 2012 the funds received from GSK to finance the extension were classified in other current liabilities for $354,000 and long term liabilities for $2,527,000. The liability is amortized on a pro-rata basis over the expected life of the assets and proportionally based on funding received compared with the total value of the related assets. This amortization is reflected as an offset of the depreciation of the related assets (see Note 13).

In May 2008, Flamel and GSK signed an amendment to the original supply agreement, extending the supply of commercial supplies of the product through to end of 2010. In October, 2011, the Company announced that it signed a new supply agreement with GSK for the production of Coreg CR microparticles; the Company is the sole supplier of Coreg CR microparticles for GSK. Under the agreement, the Company will receive guaranteed minimum payments to supply Coreg CR microparticles over a period of over a minimum period of five years. No earlier than January 1, 2013, GSK may terminate the agreement at their sole discretion by giving six months written notice. *See Note 3. Subcontracting Agreement.*

Wyeth Pharmaceuticals

On September 12, 2007 the Company entered into a development and license agreement with Wyeth Pharmaceuticals, (‘Wyeth’) now part of Pfizer Inc., whereby the Company agreed to license its Medusa technology for the development and licensing of a marketed protein. The Company received an upfront fee and may receive development fees, milestones and royalties on the product. On September 2, 2008 Wyeth confirmed their intention to pursue the development and license agreement triggering a $500,000 payment. On November 4, 2009 Wyeth exercised the option for the licensing of Flamel technology and paid $1,000,000.

In 2010, the Company recognized research and development revenues of $353,000. The Company also recognized $221,000 of amortization of up-front payment and option payment.

In 2011, the Company recognized research and development revenues of $75,000. The Company also recognized $665,000 of amortization of up-front payment and option payment, of which $425,000 relates to accelerated amortization due to termination.

In March 2012 the Company announced that the arrangement with Pfizer was discontinued.

Merck Serono, a division of Merck KGaA

On December 20, 2007 Flamel Technologies entered into a relationship with Merck Serono, a division of Merck KGaA, to investigate the applicability of Flamel's Medusa technology for the extended release of a therapeutic protein of Merck Serono's portfolio.

In consideration of the agreement signed in 2007, Merck Serono made an upfront payment of $2.7 million for investigating the therapeutic protein, which has been amortized over the initial feasibility period. In February 2009 Merck Serono exercised the option to license our technology triggering a payment of $ 6,500,000 (€5,000,000). Under the terms of the agreement, the Company is eligible to receive up to €41 million ($53 million) in milestone payments upon certain agreed-upon development events.

In 2010, the Company recognized research and development revenues of $4,091,000. The Company also recognized $5,437,000 of milestones payments and $1,327,000 of amortization of the initial up-front and option payments.

In 2011, the Company recognized research and development revenues of $2,398,000. The Company also recognized $1,391,000 of amortization of the initial up-front and option payments.

On November 2, 2012, Flamel received notice from Merck Serono to terminate for convenience the development and license agreement. For the year 2012, the Company recognized $2,745,000 of amortization of the initial up-front and option payments, of which $1,426,000 relates to accelerated amortization due to termination.

Baxter Healthcare Inc.

On June 19, 2009 the Company entered into agreement with Baxter Healthcare Inc., to formulate controlled release applications of blood clotting factor replacement therapies using Flamel's Medusa® technology. In consideration of this agreement the Company received an access fee of $3,600,000 (€2,500,000).

In 2010, the Company recognized research and development revenues of $406,000. The Company also recognized $1,578,000 of amortization of the initial up-front fee.

In 2011, the Company recognized license revenues of $871,000 as amortization of the initial up-front fee. In October 2011 the Company announced that the agreement had been terminated.

Eagle Pharmaceuticals Inc

On October 12, 2011 the Company entered into a license and development agreement with Eagle Pharmaceuticals for the development of a Medusa-based hydrogel depot formulation of the small molecule antibiotic, tigecycline. In consideration of this agreement, the Company recognized research and development revenues of $345,000. Milestone payments amounting to $1.2 million (€0.9 million) will be received upon achievement of certain development and commercial events.

In 2012, the Company recognized research and development revenues of $659,000. The Company also recognized $43,000 of amortization of the initial up-front fee.

Pfizer Inc

The company entered into research collaboration with Pfizer Inc. to assess the applicability of the Medusa platform to certain molecules in development. Under this collaboration, the Company recognized research and development revenues of $333,000 in 2010 and $18,000 in 2011. In March 2012 the Company announced that the collaboration with Pfizer had been discontinued.

Corning

In December 1998, the Company signed a long-term research and product development agreement with Corning France and Corning Incorporated. Pursuant to the terms of this agreement, Flamel receives royalties on the sales of Corning products that utilize Flamel's innovations.

The Company recognized royalties on Corning's sales of $440,000 in 2010, $372,000 in 2011 and $152,000 in 2012.

Others

The Company recognized license and research and development revenues with undisclosed partners for an amount of $5,958,000 in 2010, $4,808,000 in 2011 and $5,877,000 in 2012.

5. Research and Development expenses

Total research and development expenditures can be disaggregated in the following significant type of expenses ($USD in millions):

	2010	2011	2012
Research and Development Expenses	37.2	33.7	32.7
R&D Tax Credit	(7.6)	(6.0)	(6.5)
Grants	(0.9)	(1.7)	(0.1)
Total	28.7	25.1	26.1

As of December 31, 2012 the Company recognized to the income statement unconditional grants for a total of $103,000.

6. Stock based compensation:

6.1 ASC 718

The Company applies the provisions of ASC 718 in accounting for its stock based compensation. The fair value of each option and warrant granted during the year is estimated on the date of grant using the Black-Scholes option pricing model. Option valuation models require the input of subjective assumptions and these assumptions can vary over time. The weighted-average assumptions on grants made in each of the following years were:

	Year Ended December 31		
	2010	2011	2012
Weighted-average expected life (years)	4.56	4.00	5.70
Expected volatility rate	60.5%	63.6%	62.5%
Expected dividend yield	-	-	-
Risk-free interest rate	1.43%	0.83%	0.95%
Forfeiture rate	-	-	-

We base our determination of expected volatility predominantly on the implied volatility of our traded options with consideration of our historical volatilities. Given the limited historical data and the grant of stock options and warrants to a limited population, the simplified method has been used to calculate the expected life.

Stock based compensation expense recognized was as follows:

(In thousands of U.S dollars except per share data)	Options			Free of charge share awards			Warrants			Total		
	2010	2011	2012	2010	2011	2012	2010	2011	2012	2010	2011	2012
Research and development	400	332	419	831	897	649	-	-	-	1,231	1,229	1,068
Cost of goods sold	9	3	2	113	89	46	-	-	-	122	91	49
Selling, general and administrative	615	461	1,280	677	671	464	525	327	179	1,817	1,459	1,923
Total stock-based compensation expense	1,024	796	1,701	1,621	1,657	1,160	525	327	179	3,170	2,779	3,040
Effect on earnings per share												
Basic	0.04	0.03	0.07	0.07	0.07	0.05	0.02	0.01	0.01	0.13	0.11	0.12
Diluted	0.04	0.03	0.07	0.07	0.07	0.05	0.02	0.01	0.01	0.13	0.11	0.12

As of December 31, 2012, the projected compensation expense related to non vested options or warrants amounted to $2,158,000 and is expected to be recognized over a weighted average period of 1.36 years.

6.2 Warrants

The summary of warrants activity is as follows:

	Warrants Outstanding	Weighted Average Exercise Price in U.S dollars [1]	Weighted Average Exercise Price in Euros
Balance at January 1, 2010	630,500	$ 11.73	€ 8.24
Warrants granted	250,000	$ 6.97	€ 5.44
Warrants cancelled	130,500	$ 25.11	€ 18.62
Balance at December 31, 2010	750,000	$ 7.82	€ 5.50
Warrants granted	300,000	$ 5.03	€ 3.54
Warrants cancelled	150,000	$ 6.94	€ 4.98
Balance at December 31, 2011	900,000	$ 6.89	€ 4.85
Warrants granted	3,300,000	$ 8.63	€ 6.61
Warrants reintegrated	100,000	$ 6.65	€ 4.97
Warrants cancelled	200,000	$ 10.20	€ 6.57
Balance at December 31, 2012	4,100,000	$ 6.89	€ 4.85

[1] Historical exchange rate at date of grant

No warrants were exercised in 2010, 2011 and 2012.

Exercise prices and intrinsic value for warrants outstanding as of December 31, 2012 were as follows:

	Warrants Outstanding				Warrants Exercisable		
Range of exercise prices in euros	Number of shares	Weighted average remaining contractual life	Weighted average exercise price in euros	Weighted average intrinsic value in euros	Number of shares	Weighted average exercise price in euros	Weighted average intrinsic value in euros
0 to 4.50	550,000	1.57	3.98	-	550,000	3.98	-
5.44 to to 6.57	2,450,000	4.82	5.67	-	2,450,000	5.67	-
6.58 to 8.52	1,100,000	5.20	8.42	-	1,100,000	8.42	-
	4,100,000	**4.48**	**6.10**		**4,100,000**	**6.44**	-

The total fair value of warrants vested during 2010 amounted to €472,000 or $626,000 (average exchange rate of the year).

The total fair value of warrants vested during 2011 amounted to €257,000or $358,000 (average exchange rate of the year).

The total fair value of warrants vested during 2012 amounted to €271,000or $348,000 (average exchange rate of the year).

Intrinsic value represents the variance between the share price and the exercise price. As of December 31, 2012 the aggregate intrinsic value of warrants outstanding amounted to zero.

6.3 Stock Options

The activity under the option plans is as follows:

	Shares Available for Grant	Options Granted and Outstanding	Weighted Average Exercise Price in U.S dollars[1]	Weighted Average Exercise Price in Euros
Balance at January 1, 2010	45,000	3,110,990	$ 14.96	€ 12.08
Options authorized	750,000	-	-	-
Granted	(305,000)	305,000	$ 6.91	€ 5.21
Exercised	-	(63,000)	$ 4.01	€ 5.75
Forfeited	(15,000)	(254,500)	$ 8.51	€ 7.65
Balance at December 31, 2010	475,000	3,098,490	$ 14.69	€ 11.71
Options authorized				
Granted	(200,000)	200,000	$ 4.39	€ 3.28
Exercised	-	(44,200)	$ 1.48	€ 1.63
Forfeited	-	(113,300)	$ 8.93	€ 7.49
Balance at December 31, 2011	275,000	3,140,990	$ 14.65	€ 11.66
Options authorized	1,000,000	-	-	-
Granted	(550,000)	550,000	$ 5.97	€ 4.67
Exercised	-	(195,000)	$ 2.04	€ 2.33
Forfeited	10,000	(223,500)	$ 16.88	€ 13.69
Balance at December 31, 2012	735,000	3,272,490	$ 13.79	€ 10.90

[1] Historical exchange rate at date of grant

The total intrinsic value of options exercised during 2010 amounted to €174,000 or $256,000 (historical exchange rate at date of exercise).

The total intrinsic value of options exercised during 2011 amounted to €111,000 or $149,000 (historical exchange rate at date of exercise).

The total intrinsic value of options exercised during 2012 amounted to €735,000 or $973,000 (historical exchange rate at date of exercise).

Stock options outstanding at December 31, 2012, which expire from 2013 to 2022, had exercise prices ranging from €3.28 to € 25.39. The weighted average remaining contractual life of all options is 4.34 years. As of December 31, 2012, there were 3,272,490 outstanding options at a weighted average exercise price of €10.90, of which 2,476,240 were exercisable at a weighted average price of €12.97. Exercise prices and intrinsic value for options outstanding as of December 31, 2012 were as follows:

	Stock Options Outstanding				Stock Options Exercisable		
Range of exercise prices in euros	Number of shares	Weighted average remaining contractual life	Weighted average exercise price in euros	Weighted average intrinsic value in euros	Number of shares	Weighted average exercise price in euros	Weighted average intrinsic value in euros
0 to 3.28	195,000	8.45	3.28	-	48,750	3.28	-
4.03 to 5.44	1,385,000	7.04	4.73	-	735,000	4.74	-
6.40 to 12.02	123,500	1.62	10.93	-	123,500	10.93	-
12.86 to 16.23	1,040,990	2.60	14.46	-	1,040,990	14.46	-
19.2 to 25.39	528,000	2.58	22.85	-	528,000	22.85	-
	3,272,490	**4.34**	**10.90**	**0.00**	**2,476,240**	**12.97**	**0.00**

The total fair value of options vested during 2010 amounted to €1,424,000 or $1,889,000 (average exchange rate of the year).

The total fair value of options vested during 2011 amounted to €473,000 or $659,000 (average exchange rate of the year).

The total fair value of options vested during 2012 amounted to €846,000 or $1,088,000 (average exchange rate of the year).

The aggregate intrinsic value of options outstanding or exercisable amounted to zero.

6.4 Free share award

The activity under the free share award plans is as follows:

	Free of Charge Share Award Available for Grant	Free of Charge Share Award Granted and Outstanding	Weighted Average Fair Value at grant date in U.S dollars[1]	Weighted Average Fair Value at grant date in Euros
Balance at January 1, 2010	10,650	573,350	$ 6.68	€ 4.73
Options authorized	200,000	-	-	-
Granted	(230,000)	230,000	$ 7.01	€ 5.29
Exercised	-	(240,050)	$ 5.91	€ 4.39
Forfeited	37,500	(37,500)	$ 5.93	€ 4.39
Cancelled	3,300	(3,300)	$ 5.17	€ 4.03
Balance at December 31, 2010	18,150	522,500	$ 7.25	€ 5.16
Options authorized	200,000	-	-	-
Granted	(200,000)	200,000	$ 4.39	€ 3.28
Exercised	-	(272,400)	$ 7.47	€ 5.07
Forfeited	8,450	(8,450)	$ 7.22	€ 5.18
Cancelled	1,000	(1,000)	$ 7.45	€ 5.06
Balance at December 31, 2011	26,600	440,650	$ 5.81	€ 4.36
Options authorized	200,000	-	-	-
Granted	(189,700)	189,700	$ 3.07	€ 2.38
Exercised	-	(258,150)	$ 6.52	€ 4.92
Forfeited	21,550	(21,550)	$ 5.79	€ 4.35
Balance at December 31, 2012	58,450	350,650	$ 3.81	€ 2.88

[1] Historical exchange rate at date of grant

As of December 31, 2010 the total fair value (or intrinsic value) of Free Share Award outstanding amounted to €2,697,000 or $3,745,000 (historical exchange rate at date of grant).

As of December 31, 2011 the total fair value (or intrinsic value) of Free Share Award outstanding amounted to €1,774,000 or $2,296,000 (historical exchange rate at date of grant).

As of December 31, 2012 the total fair value (or intrinsic value) of Free Share Award outstanding amounted to €1,009,000 or $1,336,000 (historical exchange rate at date of grant).

7. Cash and Cash Equivalents:

Cash consists of cash on deposit and fixed term investments held in several major banks, and cash on hand. The components of cash and cash equivalents were as follows:

(In thousands of U.S. dollars)	December 31, 2011	December 31, 2012
HSBC	$ 2,785	$ 880
Credit Agricole	630	641
Commerce Bank .	-	1,057
Citibank .	-	159
Other .	41	5
Total cash and cash equivalents	$ 3,456	$ 2,742

8. Marketable securities:

Marketable securities are classified as available-for-sale securities and are recorded at fair market value. Unrealized gains and losses are recorded as other comprehensive income in shareholder's equity, net of income tax effects.

For the year ended December 31, 2010, 2011 and 2012 marketable securities amounted respectively to $23,160,000, $21,036,000 and $6,413,000.

As of December 31, 2010, December 31, 2011 and December 31, 2012 there were no unrealized gains or losses.

(in thousands of U.S dollars)	Fair value		Value at cost		Unrealized Gains (Losses)	
	2011	2012	2011	2012	2011	2012
Credit Agricole securities	17,802	6,413	17,802	6,413	-	-
HSBC securities	3,233	-	3,233	-	-	-
Total	21,035	6,413	21,035	6,413	-	-

Gross realized gains on sales of these available-for-sale securities amounted to $74,000, $41,000 and $6,000 for the years ended December 31, 2010, 2011 and 2012 respectively.

(in thousands of U.S dollars)	Proceeds from sales		Purchase of securities		Gross gains (Losses)	
	2011	2012	2011	2012	2011	2012
Credit Agricole securities	5,775	15,143	8,062	3,573	10	3
HSBC securities	20,607	3,216	16,953	-	31	3
Total	26,382	18,359	25,015	3,573	41	6

9. Inventory:

The components of inventories were as follows:

(In thousands of U.S. dollars)	December 31, 2011	2012
Raw materials	921	894
Finished goods	754	626
Inventories, net	1,675	1,520

10. Prepaid expenses and other current assets:

The components of prepaid expenses and other current assets were as follows:

(In thousands of U.S. dollars)	December 31, 2011	2012
Valued-added tax recoverable	1,028	1,013
Prepaid expenses	832	906
Advance to suppliers	352	324
Grants recoverable	430	71
Total Prepaid expenses and other current assets	2,642	2,314

11. Property and Equipment:

The components of property and equipment were as follows:

(In thousands of U.S. dollars)	December 31, 2011	2012
Land and buildings	10,132	10,332
Laboratory equipment	28,639	29,314
Office and computer equipment	4,641	5,135
Furniture, fixtures and fittings	19,956	20,697
Construction in progress	-	-
Total property and equipment	63,368	65,478
Less accumulated depreciation and amortization	(43,985)	(47,240)
Property and equipment, net	19,383	18,238

Depreciation expense related to property and equipment amounted to $4,696,000, $3,346,000 and $3,183,000 for the years ended December 31, 2010, 2011 and 2012, respectively.

Property and Equipment include costs of $509,000 and $507,000 at December 31, 2011 and 2012 that are related to capitalized lease assets. Accumulated amortization of these leased assets was approximately $173,000 and $211,000 at December 31, 2011 and 2012, respectively. Depreciation expense on assets held under capital leases is included in total depreciation expense for the years ended December 31, 2010, 2011 and 2012 and amounted to $47,000, $56,000 and $44,000 respectively.

12. Goodwill and intangible assets

	December 31,							
	2011				2012			
(In thousands of U.S. dollars)	Gross carrying amount	Accumulated amortization	Impairment	Intangible assets, net	Gross carrying amount	Accumulated amortization	Impairment	Intangible assets, net
Goodwill	$ 534	(534)	-	-	$ 544	(544)	-	-
Goodwill Eclat acquisition	-	-	-	-	18,491	-	-	18,491
Total Goodwill	$ 534	$ (534)	$ -	$ -	$ 19,035	$ (544)	$ -	$ 18,491
In-progess R&D	-	-	-	-	47,309	-	(7,170)	40,139
License	-	-	-	-	1,973	(523)		1,450
Total Intangible assets	$ -	$ -	$ -	$ -	$ 49,282	$ (523)	$ (7,170)	$ 41,589

See note 2 – Business combinations.

13. Accrued Expenses

Accrued expenses consist mainly of expenses related to bonuses, paid vacations, compensatory leaves and related social charges.

Accrued expenses comprises of the following:

	December 31,	
(In thousands of U.S. dollars)	2011	2012
Accrued compensation	2,037	1,671
Accrued social charges	3,441	3,193
Other	-	149
Total accrued expenses	5,478	5,013

14. Other current and Long Term liabilities:

14.1. Other current liabilities:

Other current liabilities comprise the following:

	December 31,	
(In thousands of U.S. dollars)	2011	2012
Funding from partner GSK short term	734	669
Employee service award provision short term	641	263
Valued-added tax payable	251	201
Provision for retirement indemnity short term	129	-
Conditional grants	240	-
Total Other current liabilities	1,995	1,133

In connection with the 2004 supply agreement with GSK (see Note 4), the Company received funds to finance facilities related assets. A total of $8,188,000 has been spent on the acquisition of buildings and fixtures and a total of $11,138,000 has been spent on behalf of GSK for the purchase of production equipment. As of December 31, 2012 the funds received from GSK to finance the acquisition of assets owned by Flamel are classified as a current liability for $316,000 and as a long term liability for $3,818,000. In July 2006, Flamel and GSK entered into a side agreement to the original agreement whereby GSK partially sponsored the extension of the Micropump development facility (see Note 4). This facility was completed in March 2008. As of December 31, 2007, the Company had received all installments from GSK for financing of this project. The total installments amounted to $8,097,000. As of December 31, 2012, the funds received from GSK are classified as a current liability for $353,000 and as a long term liability for $2,527,000 (see Note 14.2).

The liability is amortized on a pro-rata basis over the expected life of the related assets and reflected as an offset of the depreciation of the related assets (see Note 4).

The Service award provision is accrued over the respective service period (5, 10, 15 and 20 years) using actuarial assumptions and calculations as for the lump sum retirement indemnity (see Note 21).

For the year ended December 31, 2011 the provision for service award amounted to $2,876,000 of which $641,000 is short term. For the year ended December 31, 2012 the provision amounted to $3,031,000 of which $263,000 is short term.

Conditional grants were received from local authorities for a total of $1.8 million in 2008 and 2009 to partly finance investments. The grants are conditional on completion of the total investment programme and ongoing employment for a period of three to five years. The Company recognizes conditional grants as an offset to operating expenses once all conditions stated in the grant have been met. As of December 31, 2011 the Company recognized $2,128,000 and the remainder is classified as short term liabilities for an amount of $240,000. As of December 31, 2012 all amounts related to the conditional grants has been recognized.

14.2. Other long term liabilities

Other long term liabilities are composed of the following:

	December 31,	
(In thousands of U.S. dollars)	**2011**	**2012**
Funding from partner GSK long term	6,906	6,345
Provision for retirement indemnity (see note 21)	1,978	2,875
R&D credit tax financing long term	6,682	12,661
Employee service award provision long term	2,235	2,768
Other	22	31
Total Other long term liabilities	17,823	24,680

Funding from GSK long term amounted to $3,818,000 in connection with the supply agreement signed in December 2004 and relates to the acquisition of buildings and fixtures and $2,527,000 in connection with the side agreement to the original agreement, signed in July 2006 (see Note 14.1).

In 2011, the Company obtained an advance from OSEO, a governmental agency supporting innovation, for $6,813,000 (€5,164,000) secured against the research tax credits due to the company by the tax authorities for expenditure incurred in 2010 (see Note 19). The interest rate applied is the monthly average of the Euro Interbank Offered Rate (EURIBOR) plus 0.9%. In 2012 the operation was renewed with the same conditions and secured against the research credit tax from 2011. The Company received an amount of $5,848,000 (€4,432,000). As of December 31, 2011 the total funding was classified as a long term liability for an amount of $6,682,000. As of December 31, 2012 the total funding was classified as a long term liability for an amount of $12,661,000.

15. Deferred Revenue:

Current portion of deferred revenue comprises of upfront licensing fees which are recognized over the development period of the contract. For the year ended December 31, 2011 deferred revenues amounted to $4,367,000 and $795,000 for the year ended December 31, 2012. These deferred revenues result from the upfront license fees received in 2011 from undisclosed partners.

16. Long-term Debt:

Long-term debt comprises:

(In thousands of U.S. dollars)	December 31, 2011	2012
Oseo Anvar loans (a)	1,807	2,751
French Ministry of Research (b)	1,908	1,945
Acquisition liability contingent consideration (c)	-	24,063
Acquisition liability note (c)	-	5,713
Acquisition liability warrant consideration (c)	-	2,157
Total	3,715	36,629
Current portion	2,026	3,351
Long-term portion	1,689	33,278

(a) OSEO Anvar is an agency of the French government that provides financing to French companies for research and development. At December 31, 2011 and 2012, the Company had outstanding loans from Anvar of $1,807,000 and $2,751,000, respectively for various programs. In 2012, the Company received $1,029,000 for two of these projects. These loans do not bear interest and are repayable only in the event the research project is technically or commercially successful. Potential repayment is scheduled to occur from 2013 through 2019.

(b) In 2002, the Company received a loan of $464,000 from the French Ministry of Research on a research project (the “Proteozome” project) related to the development of new Medusa applications. Pursuant to the agreement, the Company is granted a loan equal to 50% of the total expenses incurred on this project over a three-year period beginning on January 2, 2002. The remainder of the advance of $1,707,000 was received in 2005. This loan is due for repayment in 2013. The loan is non-interest bearing and is repayable only in the event the research project is technically or commercially successful.

(c)The Acquisition liability relates to the acquisition by the Company through its wholly owned subsidiary Flamel US Holdings, Inc., or Flamel US, all of the membership interests of Éclat Pharmaceuticals, LLC (*see note 2 Business combinations*). In exchange for all of the issued and outstanding membership interests of Éclat Pharmaceuticals, Flamel US provided consideration consisting of:

- a $12 million senior, secured six-year note that is guaranteed by the Company and its subsidiaries and secured by the equity interests and assets of Éclat;
- two warrants to purchase a total of 3,300,000 American Depositary Shares, each representing one ordinary share of Flamel (“ADSs”); and
- a commitment to make earn out payments of 20% of any gross profit generated by certain Éclat Pharmaceuticals launch products and to pay 100% of any gross profit generated by Hycet® up to a maximum of $1 million. The Purchase Agreement also contains certain representations and warranties, covenants, indemnification and other customary provisions.

As of December 31, 2012, the fair value of the note was estimated using a probability-weighted discounted cash flow model. This fair value measurement is based on significant inputs not observable in the market and thus represents a level 3 measurement as defined in ASC 820. The key assumptions are as follows: 20% discount rate, 63% probability of success. The note has no early redemption premium.

As of December 31, 2012, the fair value of the warrants was determined by using a Black-Scholes option pricing model with the following assumptions:

Share price	$ 3.03
Risk-free interest rate	0.77%
Dividend yield	-
Expected volatility	53.75%
Expected term	5.2 years

Pursuant to guidance of ASC 815-40-15-7(i), the Company determined that the Warrants issued in March 2012 as consideration for the acquisition of Éclat could not be considered as being indexed to the Company's own stock, on the basis that the exercise price for the warrants is determined in U.S. dollars, although the functional currency of the Company is the Euro. The Company determined that these warrants should be accounted as a debt instrument.

As of December 31, 2012, the deferred consideration fair value was estimated by using a discounted cash flow model based on probability adjusted annual gross profit of each of the Éclat Pharmaceuticals products. A discount rate of 20% has been used, except for Hycet for which a discount rate of 13% has been retained.
Total future payments on long-term debt for the next five years ending December 31 (assuming the underlying projects are commercially or technically successful for governmental research loans) are as follows:

(In thousands of U.S. dollars)	**December 31,**
2013	3,351
2014	5,806
2015	14,505
2016	14,944
2017	8,255

17. Capital lease obligations:

The Company leases certain of its equipment under capital leases. Each lease contract generally has a term of four years with a purchase option. No specific restrictions or guarantee provisions are included in the arrangement.

Future payments on capital leases for the years ending December 31 are as follows:

(In thousands of U.S. dollars)	**December 31,**
2013	87
2014	87
2015	85
2016	13
Total	274
Less amounts representing interest	(18)
Future payments on capital leases	256
Less current portion	77
Long term portion	179

Interest paid in the years ended December 31, 2010, 2011 and 2012 was approximately $9,000, $20,000 and $14,000, respectively.

18. Earnings Per Share:

The following is a reconciliation of the numerators and denominators of the basic and diluted earnings per share computations:

(In thousands, except per share amounts)	Year ended December 31, 2010	2011	2012
Numerator:			
Net income (loss)	($ 8,975)	($ 8,774)	($ 3,228)
Denominator:			
Weighted average shares outstanding used for basic earnings (loss) per share	24,411,158	24,668,579	25,135,416
Effect of dilutive securities:			
Stock-options and warrants	-	-	-
Weighted average shares outstanding and dilutive securities used for diluted earnings (loss) per share	24,411,158	24,668,579	25,135,416
Basic earnings (loss) per share	($ 0.37)	($ 0.36)	($ 0.13)
Diluted earnings (loss) per share	($ 0.37)	($ 0.36)	($ 0.13)

For the years ended December 31, 2010, 2011 and 2012, the effects of dilutive securities were excluded from the calculation of earnings per share as a net loss was reported in these periods.

Options to purchase 6,576,240 shares of common stock at an average of €8.99 per share were outstanding during 2012, but were not included in the computation of diluted EPS because the exercise price was greater than the average market price of common shares. The options, which expire in December 2022, were still outstanding at the end of year 2012.

19. Shareholders' Equity:

191. Preemptive subscription rights:

Shareholders have preemptive rights to subscribe for additional shares issued by the Company for cash on a pro rata basis when the Company makes a share offering. Shareholders may waive such preemptive subscription rights at an extraordinary general meeting of shareholders under certain circumstances. Preemptive subscription rights, if not previously waived, are transferable during the subscription period relating to a particular offer of shares.

19.2. Dividends:

Dividends may be distributed from the statutory retained earnings, subject to the requirements of French law and the Company's by-laws. The Company has not distributed any dividends since its inception, as the result of an accumulated statutory deficit of approximately $161.1 million at December 31, 2012. Dividend distributions, if any, will be made in euros. The Company has no plans to distribute dividends in the foreseeable future.

19.3. Warrants:

The effects of applying the fair value method provided in accordance with ASC 718 are shown in Note 6.

On June 24, 2009 the Company authorized the Directors of the Company, to subscribe to 250,000 warrants for a subscription price of €0.74 per warrant ($1.03). Each warrant is exercisable to purchase one Share at a price of €4.50 ($6.29). These warrants are issued for a four-year period and will vest over one year from the date of issuance. These warrants were subscribed in July 2009.

On June 25, 2010 the Company authorized the Directors of the Company, to subscribe to 250,000 warrants for a subscription price of €0.70 per warrant ($0.90). Each warrant is exercisable to purchase one Share at a price of €5.44 ($6.68). These warrants are issued for a four-year period and will vest over one year from the date of issuance. These warrants were subscribed in July 2010.

On June 24, 2011 the Company authorized the Directors of the Company, to subscribe to 350,000 warrants for a subscription price of €0.47 per warrant ($0.67). Each warrant is exercisable to purchase one Share at a price of €3.54 ($5.03). These warrants are issued for a four-year period and will vest over one year from the date of issuance. 300,000 warrants were subscribed in July 2011.

On March 13, 2012, in connection with the acquisition of Éclat Pharmaceutical, Flamel issued to Breaking Stick LLC (formerly Éclat Holdings LLC), two six-year warrants to purchase an aggregate of 3,300,000 ADSs, each representing one ordinary share, of Flamel. One warrant is exercisable for 2,200,000 ADSs at an exercise price of $7.44 per ADS, and the other warrant is exercisable for 1,100,000 ADSs at an exercise price of $11.00 per ADS. Pursuant to the guidance of ASC 815-40-15-7 the Company determined that the warrants should be accounted for as a liability (*see note 16 Long Term Debt*).
On exercise of warrants by beneficiaries, the Company issues new shares.

19.4. Stock options:

The Company issued stock options under plans approved by shareholders in 1990, 1993, 1996, 2000, 2001, 2003, 2004, 2005, 2007, 2010 and 2012. The option terms provide for exercise within a maximum 10-year term as from the date of grant. Generally, each option vests no more than four years from the date of grant.

In January 1997, the French parliament adopted a law that requires French companies and beneficiaries to pay social contributions, which generally represent 45% of the taxable salary, on the difference between the exercise price of a stock option and the fair market value of the underlying shares on the exercise date if the beneficiary sells the stock before a four-year period following the grant of the option (five years for options granted before 2000). This law is consistent with personal income tax law that requires individuals to pay income tax on the difference between the option exercise price and the fair value of the shares at the sale date if the shares are sold within four years of the option grant. The law applies to all options exercised after January 1, 1997. The Company has instituted an internal rule whereby, whilst remaining an employee of the Company, an individual may not sell the underlying share within four years of the option being granted.

In December 2007, the French parliament adopted a law that requires French companies to pay an additional social security contribution of 10% for each option granted, based on either the fair value of the option or 25% of share price at date of grant. This is applicable on all options granted since October 16, 2007. In December 2010, the French parliament introduced a contribution rate of 14% depending on the value of the grant. In July 2012 this r ate was increased to 30%.

On exercise of stock options by beneficiaries, the Company issues new shares.

19.5. Free Share Awards

On June 25, 2010, the shareholders of the Company authorized the issuance of 200,000 new shares that the Board of Directors was authorized to award and issue free of charge to officers and employees of the Company as compensation for services rendered. Under the terms of the awards the shares are definitively owned by the beneficiaries two years following their allocation and the Company issues new shares. The beneficiaries are required to retain the shares for two additional years.

On June 24, 2011, the shareholders of the Company authorized the issuance of 200,000 new shares that the Board of Directors was authorized to award and issue free of charge to officers and employees of the Company as compensation for services rendered. Under the terms of the awards the shares are definitively owned by the beneficiaries two years following their allocation and the Company issues new shares. The beneficiaries are required to retain the shares for two additional years.

On June 22, 2012, the shareholders of the Company authorized the issuance of 200,000 new shares that the Board of Directors was authorized to award and issue free of charge to officers and employees of the Company as compensation for services rendered. Under the terms of the awards the shares are definitively owned by the beneficiaries two years following their allocation and the Company issues new shares. The beneficiaries are required to retain the shares for two additional years.

In December 2007, the French parliament adopted a law that requires French companies to pay an additional social contribution of 10% for each share granted, based on the share price at date of grant. In December 2010, the French parliament introduced a contribution rate of 14% depending of the value of the grant. In July 2012 the contribution rate was raised to 30%.

On April 3, 2008 the Company granted 40,000 free share awards to officers. On April 3, 2010 the Company issued 40,000 new shares related to this grant.

On December 10, 2008 the Company granted 210,000 free share awards to officers and employees. On December 10, 2010 the Company issued 200,050 new shares related to this grant. On December 10, 2012 the Company issued 5,000 new shares related to this grant.

On February 1, 2009 the Company granted 25,000 free shares to officers. As of December 31, 2011 these shares were cancelled.

On December 11, 2009 the Company granted 295,000 free share awards to officers and employees. On December 11, 2011 the Company issued 267,400 new shares related to this grant.

On December 6, 2010 the Company granted 230,000 free shares awards to officers and employees. On December 6, 2012 the Company issued 208,150 new shares related to this grant.

On December 7, 2011 the Company granted 200,000 free shares to officers and employees. On December 31, 2012 the Company issued 45,000 new shares related to this grant.

On December 10, 2012 the Company granted 189,700 free shares to officers and employees.

19.6. Accumulated other comprehensive income:

The components of accumulated other comprehensive income is as follows:

	December 31,	
(In thousands of U.S. dollars)	**2011**	**2012**
Foreign currency translation	10,057	10,253
Total	10,057	10,253

20. Income taxes:

Income (loss) before income taxes comprises the following:

	Year ended December 31,		
(in thousands of U.S. dollars)	**2010**	**2011**	**2012**
France	(8,766)	(8,582)	(14,216)
United States	-	-	6,286
Total	$ (8,766)	$ (8,582)	$ (7,930)

A reconciliation of income tax benefit (provision) computed at the French statutory rate (33.33%) and the US statutory rate (40%) to the income tax benefit is as follows:

(in thousands of U.S. dollars)	Year ended December 31, 2010	2011	2012
Income tax benefit (provision) computed at the statutory rate (US & France)	2,922	2,860	2,224
Deferred Tax Allowance	(2,922)	(2,860)	(4,738)
Business Tax	(209)	(192)	(56)
Non Taxable remeasurement of fair value accounting	-	-	7,303
Temporary differences	-	-	(31)
Total	$ (209)	$ (192)	$ 4,702

License fees, milestone and royalties payments may be subject to a withholding tax depending on the tax rules of the country in which the licensee is located. In December 2009, with effect from January 1, 2010 the French authorities abolished the previous business tax and introduced the "Contribution Economique Territoriale" comprised of two components. One of these components is based upon a measure of income and therefore results in income tax accounting. For the year ended December 31, 2010, 2011 and December 31, 2012 the amount of this component was $209,000, $192,000 and $56,000 respectively.

Significant components of the Company's deferred taxes consist of the following:

(In thousands of U.S. dollars)	December 31, 2011	2012
Deferred income tax assets:		
Net taxable operating loss carry-forwards (not utilized)	53,230	65,657
Other deferred income tax assets	4,133	3,656
Valuation allowance for french activities	(57,105)	(64,356)
Net deferred income tax assets	258	4,957
Deferred income tax liabilities	(258)	(19,086)
Deferred income taxes, net	-	(14,130)

The Company has provided valuation allowances covering 100% of net deferred tax assets generated from its activities in France due to the Company's history of losses.

As of December 31, 2012, the Company had $184,716,000 in French net operating losses carry-forwards which have no expiration date, but for which annual utilization is limited to €1,000,000 plus 50% of any taxable income in excess of this threshold and $9,800,000 in US net operating losses carry-forwards which expire from 2030 to 2032, for which utilization of pre-acquisition tax losses of $4,9000,000 million is limited to $1,800,000 per year.

The increase in available net operating losses carry-forwards in 2012 is due to a tax loss $26,369,000 and the addition of pre-acquisition tax losses on acquisition of Éclat totaling $4,647,000. The French government provides tax credits to companies for spending on innovative research and development. These credits are recorded as an offset of research and development expenses (see note 5) and are credited against income taxes payable in each of the four years after being incurred or, if not so utilized, are recoverable in cash. As of December 31, 2012, Flamel had total research tax credits receivable of $20,357,000. In 2011, the Company obtained an advance from OSEO, a governmental agency supporting innovation, secured against the Research tax credit generated in fiscal year 2010. The Company renewed this financing operation in 2012 secured against the research tax credit generated for fiscal year 2011 (see Note 13.1). Generally, if these credits are not applied against future income taxes, they will be received as cash payments in the fourth year after the credit is earned.

The scheduled payments are shown in the following table

(In thousands of U.S. dollars)	December 31,
2013	6,632
Total current portion	**6,632**
2014	7,450
2015	6,275
Total long term portion	**13,725**
Total	**20,357**

21. Employee Retirement plans:

In accordance with French law, post-retirement benefits for most of the Company's employees are sponsored by the relevant government agencies in France. The Company's liability with respect to these plans is generally limited to specific monthly payroll deductions. Consequently, there is no additional liability in connection with these plans. Expenses recognized for these plans were $1,372,000 in 2012, $1,432,000 in 2011 and $1,498,000 in 2010.

French law requires the Company to provide for the payment of a lump sum retirement indemnity to French employees based upon years of service and compensation at retirement. Benefits do not vest prior to retirement. The Company's benefit obligation was $2,819,000, $2,106,000 and $1,881,000 as of December 31, 2012, 2011 and 2010, respectively. Any actuarial gains or losses are recognized in the period when they occur.

In 2008 and 2010, the French Government reinforced legislation regarding an employer's ability to make employees retire and the final age for retirement. As such the retirement indemnity has been calculated on the assumption of voluntary retirement and the impact on the benefit obligation was recognized as an actuarial loss.

The benefit obligation is calculated as the present value of estimated future benefits to be paid, using the following assumptions:

	2010	2011	2012
Average increase of salaries	3%	3%	3%
Discounted interest rate	4.75%	4.5%	3%
Turn over	actuarial standard and average of the last 5 years	actuarial standard and average of the last 5 years	actuarial standard and average of the last 5 years
Age of retirement	60 to 65 years actuarial standard based on age and professional status	60 to 65 years actuarial standard based on age and professional status	60 to 65 years actuarial standard based on age and professional status

Changes in the funded status of the benefit plans were as follows:

	December 31,	
In thousands of U.S. dollars	**2011**	**2012**
Benefit obligations at beginning of year	1,880	2,106
Service cost	166	162
Interest cost	93	91
Plan amendments	-	-
Benefits paids	(10)	(267)
Actuarial loss (gain)	58	723
Exchange rate changes	(81)	4
Benefit obligations at end of year	2,106	2,819

The Company does not have a funded benefit plan and the lump sum retirement indemnity is accrued on the balance sheet as a liability.

The future expected benefits to be paid over the next five years and for the five years thereafter is as follows:

Future expected payment of benefits: **In thousands of U.S. dollars**	Year Ending:
	12/31/2013 -
	12/31/2014 60,711
	12/31/2015 202,173
	12/31/2016 234,059
	12/31/2017 -
	Next 5 Years 530,305

In the United States, the Company sponsors a defined contribution retirement plan for certain employees located in the United States. The contribution is the lesser of 25% of an employee's wages or $49,000 in 2011 and 2012. The Company made and accrued contributions of approximately $140,000 in 2012, $55,000 in 2011 and $72,000 in 2010.

22. Fair value of financial instruments:

At December 31, 2011 and 2012, the carrying values of financial instruments such as cash and cash equivalents, trade receivables and payables, other receivables and accrued liabilities and the current portion of long-term debt approximated their market values, based on the short-term maturities of these instruments.

As noted in Note 8, the company calculates fair value for its marketable securities based on quoted market prices for identical assets and liabilities which represents Level 1 of ASC 820-10 fair value hierarchy.

At December 31, 2011 and 2012 the fair value of long-term debt and long term receivables was comparable with their carrying values.

The following table presents information about the Company securities based on quoted market prices for identical assets and liabilities for 2012 and indicates the fair value hierarchy of the valuation techniques utilized to determine such fair value.

(in thousands)		Fair Value Measured and Recorded Using			Operational Gain (losses) recognized in earnings	Financial Gain (losses) recognized in earnings	
	Net Carrying Value as of December 31, 2012	Level 1	Level 2	Level 3			Total
Assets							
Cash and cash equivalent	2,742	2,742	-	-	-	-	-
Marketable securities	6,413	6,413	-	-	-	-	-
Liabilities							
Acquisition liability contingent consideration (a)	24,063	-	-	24,063	14,009	(4,834)	9,175
Acquisition liability note (b)	5,713	-	-	5,713	794	(880)	(86)
Acquisition liability warrant consideration (c)	2,157	-	-	2,157	9,070	838	9,908

The fair value of the financial instruments in connection with the acquisition of Éclat (*see note 2 Business Combinations*) are estimated as follows:

(a) Acquisition liability deferred consideration: the fair value is estimated using a discounted cash flow model based on probability adjusted projected annual gross profit of each of the products which formed the project portfolio at the time of acquisition of Éclat Pharmaceuticals (*Note 16* Long Term Debt).

The fair value of the deferred consideration will change over time in accordance with the changes in market conditions and thus business plan projections as the relate to market size, market share, product pricing, competitive landscape, gross profit margins expected for each of the products.

(b) Acquisition liability Note: the Company uses a probability-weighted discounted cash flow model (*see note 16 Long Term Debt*).

(c) Acquisition liability warrant consideration: the Company uses a Black-Scholes option pricing model. The fair value of the warrant consideration will change over time depending on the volatility and share price at balance sheet date (*see note 16 Long Term Debt*).

23. Commitments and Contingencies:

23.1. Capital leases

The Company currently has commitments regarding capital leases as described in Note 16.

23.2. Operating leases

The Company leases its facilities and certain equipment under non-cancelable operating leases, which expire through 2017. Future minimum lease payments under operating leases due for the fiscal years ending December 31, 2012 are as follows:

(In thousands of U.S. dollars)	December 31,
2013	991
2014	502
2015	300
2016	23
2017	17
TOTAL	1,833

Rental expense for the years ended December 31, 2010, 2011 and 2012 was approximately $1,470,000, $1,124,000 and $1,081,000 respectively.

23.3. Litigation

While we may be engaged in various claims and legal proceedings in the ordinary course of business, we are not involved (whether as a defendant or otherwise) in and we have no knowledge of any threat of, any litigation, arbitration or administrative or other proceeding that management believes will have a material adverse effect on our consolidated financial position or results of operations.

On November 9, 2007 a putative class action was filed in the United States District Court for the Southern District of New York against the Company and certain of its current and former officers entitled Billhofer v. Flamel Technologies, et al. By Order dated March 8, 2013, the Court granted the Company's motion to dismiss and the action was dismissed with prejudice and costs. The complaint purported to allege claims arising under the Securities Exchange Act of 1934 based on certain public statements by the Company concerning, among other things, a clinical trial involving Coreg CR and sought the award of damages in an unspecified amount. By Order dated February 11, 2008, the Court appointed a lead plaintiff and lead counsel in the action. On March 27, 2008, the lead plaintiff filed an amended complaint that continued to name the Company and two previously named officers as defendants and asserted the same claims based on the same events as alleged in the initial complaint. On May 12, 2008, the Company filed a motion to dismiss the action, which the Court denied by Order dated October 1, 2009. On April 29, 2010, the lead plaintiff moved to withdraw and substitute another individual as lead plaintiff and to amend the Case Management Order. On June 22, 2010, the lead plaintiff voluntarily agreed to dismiss the action against one of the previously named officers. On September 20, 2010, the Court granted the lead plaintiff's withdraw and substitution motion and the parties proceeded to engage in fact discovery. On March 6, 2012, the Court issued its opinion granting the lead plaintiff's motion for class certification, which was originally filed in October 2010 and opposed by the Company. On July 30, 2012, the Court issued an opinion denying the lead plaintiff's motion, filed on December 15, 2011, to further amend his complaint, which motion sought to substantially revise plaintiff's asserted basis for contending that the defendants should be found liable for the statements at issue. In its opinion, the Court held that the proposed amended complaint failed to properly plead a viable claim.

In May 2011, we announced the filing of a lawsuit in the U.S. District Court for the District of Columbia against Lupin for infringement of our US Patent No. 6,022,562, which is held by the Company and associated with Coreg CR. The lawsuit was dismissed in favor of a lawsuit involving the same parties for infringement of the same patent that was lodged in the U.S. District Court for the District of Maryland in May 2011. GSK is a third party defendant in the Maryland lawsuit. The lawsuit is based on the Abbreviated New Drug Application (ANDA) filed by Lupin seeking permission to manufacture and market a generic version of Coreg CR before the expiration of the patent. In August 2012, the Company concluded a settlement agreement with Lupin and the parties filed a joint stipulation of dismissal on September 11, 2012.

In September 2011, Flamel filed a lawsuit in the U.S. District Court for the District of Maryland against Anchen Pharmaceuticals, Inc., for infringement of the same patent. The lawsuit is based on the ANDA filed by Anchen seeking permission to manufacture and market a generic version of Coreg CR before the expiration of the patent. In May 2012, the Company concluded an agreement whereby Anchen agrees to pay the sum of $400,000 in settlement of the claim.

24. Industry and geographic information:

The Company operates in one segment, the development and commercialization of pharmaceutical products, including controlled-release therapeutic products based on its proprietary polymer based technology.

Revenues from GSK represented 46% of total revenues in 2010, 67% in 2011 and 63% in 2012.

Operations outside of France consist principally of the operations of Éclat pharmaceuticals acquired in March 2012 which had sales amounting to $560,000 in 2012.

Revenues by geographic location of customers are as follows:

(in thousands of U.S. dollars)	As of December 31,		
	2010	2011	2012
Revenues			
United Kingdom & Ireland	16,641	17,619	15,967
USA	3,929	3,694	3,890
France	2,425	1,763	2,930
Europe	14,098	9,524	3,313
Total Revenues	37,094	32,600	26,100

The following is a summary of long-lived assets by geographic location:

(in thousands of U.S. dollars)	As of December 31,	
	2011	2012
Long-lived assets:		
USA	$ 5	$ 60,260
France	$ 31,600	$ 31,966
Total long-lived assets	$ 31,605	$ 92,226

25. Related Party Transactions

In March 2012, we acquired, through our wholly owned subsidiary Flamel US Holdings, all of the membership interests of Éclat from Éclat Holdings, an affiliate of Flamel's largest shareholder Deerfield Capital L.P., see "note 2 - Business Combinations". Upon closing of the acquisition, Mr. Anderson, the Chief Executive Officer of Éclat, was appointed Chief Executive Officer of Flamel. Mr. Anderson retains a minority interest in Éclat Holdings, (now renamed Breaking Stick Holdings, LLC), and does not have the ability to control this entity by virtue of his minority interest.

26. Post Balance Sheet Events

On February 7, 2013 the Company announced the conclusion of a global $15 million financing arrangement with Deerfield Management, a current shareholder. Funds were received on February 4, 2013. Subject to certain limitations, the Company may use the funds for working capital, including continued investment in its research and development projects.

Consideration received was as follows:

- $12.4 million for a Facility agreement of a nominal value of $15 million, including a premium on reimbursement of $2.6 million. The principal amount of the Loan must be repaid over four years as follows: 10% on July 1, 2014, and 20%, 30% and 40% on the second, third, and fourth anniversary, respectively, of the original disbursement date of the Loan. Notwithstanding the foregoing, the entire principal amount of the Loan may be repaid in whole or in part on any interest payment date occurring after December 31, 2013. Interest will accrue at 12.5% per annum to be paid quarterly in arrears, commencing on April 1, 2013, and on the first business day of each July, October, January and April thereafter.
- $2.6 million for a Royalty agreement whereby, the Company's wholly owned subsidiary Éclat subject to required regulatory approvals and launch of product, is to pay a 1.75% Royalty of the net sales of certain products sold by Éclat and any of its affiliates until December 31, 2024.

The above commitments are secured by a Security Agreement on the intellectual property and regulatory rights related to certain 'Éclat' Products, and will be secured by Pledge agreements on certain receivables and certain physical assets owned by the Company

INCORPORATION BY REFERENCE

As provided by in the Company's Registration Statement on Form F-3, as filed with the Securities and Exchanges Commission on September 18, 2012, this report is being incorporated by reference into such registration statement.

SIGNATURES

The Registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

FLAMEL TECHNOLOGIES S.A.
(Registrant)

/s/ Michael S. Anderson

Michael S. Anderson
Chief Executive Officer

Date: April 30, 2013

EXHIBIT INDEX

Exhibit Number	Description
1.1	Revised *Statuts* or bylaws of the Company (Filed herewith)
2.1	Deposit Agreement among Flamel, The Bank of New York, as Depositary, and holders from time to time of American Depositary Shares issued thereunder (including as an exhibit the form of American Depositary Receipt) (1)
4.1*	Note Agreement among Flamel Technologies S.A., Flamel US Holdings, Inc. and Éclat Holdings, LLC, dated March 13, 2012 (2)
4.2	Guaranty of Note made by Flamel Technologies S.A. in favor of Éclat Holdings, LLC, dated March 13, 2012 (2)
4.3	Warrant to purchase 2,200,000 American Depositary Shares, each representing one Ordinary Share of Flamel Technologies S.A. (2)
4.4	Warrant to purchase 1,100,000 American Depositary Shares, each representing one Ordinary Share of Flamel Technologies S.A. (2)
4.5	Registration Rights Agreement between Flamel Technologies S.A. and Éclat Holdings, LLC, dated March 13, 2012 (2)
4.6	Registration Statement on form F-3 filed on September 18, 2012 (4)
4.7	Facility Agreement among Flamel US Holdings, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P dated December 31, 2012 (Filed herewith)
4.8*	Royalty Agreement among Eclat Pharmaceuticals LLC, Horizon Santé FLML, Sarl and Deerfield Private Design Fund II, L.P dated December 31, 2012 (Filed herewith)
4.9*	Security Agreement between Éclat Pharamaceuticals, LLC and Deerfield Private Design Fund II, L.P. and Horizon Santé FLML, Sarl, dated February 4, 2013 (Filed herewith)
8.1	List of Subsidiaries (Filed herewith)
11.1	Code of Ethics for CEO (*Directeur Généra*l), Delegated Managing Directors (*Directeurs Généraux Délégués*) and Senior Financial Officers (3)
12.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Filed herewith)
12.2	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Filed herewith)
13.1	Certification of the Chief Executive Officer pursuant to USC Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Furnished herewith)
13.2	Certification of the Principal Financial Officer pursuant to USC Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Furnished herewith)
23.1	Consent of PricewaterhouseCoopers Audit (Filed herewith).

(1) Incorporated by reference to Post-Effective Amendment No. 1 to the Company's registration statement on Form F-6 filed July 26, 2001, as amended (No. 333-12790).
(2) Incorporated by reference to the Company's Current Report on Form 6-K, filed March 21, 2012.
(3) Incorporated by reference to the Company's Annual Report on Form 20-F for the year ended December 31, 2003, filed on April 26, 2004.
(4) Incorporated by reference to the Company's registration statement on Form F-3, filed September 18, 2012 (No. 333-183961).

*Confidential treatment has been requested for the redacted portions of this agreement. A complete copy of the agreement, including the redacted portions, has been filed separately with the Securities and Exchange Commission

The registrant undertakes to provide to each shareholder requesting the same a copy of each exhibit referred to herein upon payment of a reasonable fee limited to the registrant's reasonable expenses in furnishing such exhibit.

FLAMEL TECHNOLOGIES

A joint stock company with a share capital of € € 3,099,662
Registered office located at VENISSIEUX (Rhône) Parc Club du Moulin à Vent
33, avenue du Docteur Georges Lévy

R.C.S. LYON B 379.001.530

BY LAWS

Updated as of February 26, 2013

ARTICLE 1 – FORM

The Company is a joint stock company governed by applicable laws and regulations and by these by-laws.

ARTICLE 2 – CORPORATE NAME

The corporate name is **FLAMEL TECHNOLOGIES.**

All the decisions and documents of the Company addressed to third parties, including but not limited to, letters, invoices, announcements and releases must indicate the name of the Company, immediately preceded or followed by, in legible form, the words "société anonyme" or of the initials "S.A.", the indication of the amount of the share capital and the SIREN number followed by the mention "R.C.S.", followed by the name of the city where is located the court with which the Company is registered.

ARTICLE 3 – COMPANY PURPOSE

The purpose of the Company is, in France or abroad:

- on the one hand :

- design, realization of new materials for the chemical industry as well as for other industries, specifically in the field of pharmacy, health (biomaterials), cars, aerospace, telecommunications, motorists (turbines), packing and conditioning (specifically in the field of bio-destruction) ;

- research and development of polymer and ceramic materials corresponding to identified needs ;

- filing, study, acquisition, operation and concession of patents, licenses, processes, trademarks and specialized knowledge linked with, or relating to, in any way, to the above mentioned technological fields ;

- production and sale of designed materials ;

- on the other hand:

- design, realization of new materials for the chemical industry as well as for other industries, specifically in the field of pharmacy, health (biomaterials), cars, aerospace, telecommunications, motorists (turbines), packing and conditioning (specifically in the field of bio-destruction) ;

- research and development of polymer and ceramic materials corresponding to identified

ARTICLE 4 – REGISTERED OFFICE

The registered office is at VENISSIEUX (Rhône) 33, avenue du Docteur G. Lévy - Parc Club du Moulin à vent.

Notwithstanding the power granted to the shareholders by law and these by-laws in this respect, the registered office may be transferred to any other site in the same *département* or an adjoining *département* upon a decision of the board of directors, subject to ratification at the subsequent ordinary general shareholders meeting, or any other locality by virtue of a decision of an extraordinary general shareholders meeting.

ARTICLE 5 - DURATION

The duration of the Company has started to run as of August 10, 1999 and shall expire on August 9, 2099, except in cases of early dissolution or extension.

ARTICLE 6 – SHARE CAPITAL

The share capital is set at an amount of three million and ninety nie thousand and six hundred and sixty two Euros (3,099,662€), divided into 25,415,400 shares each with a value of €0.12196.

ARTICLE 7 – FISCAL YEAR

Each fiscal year shall last one year starting January first of each year and ending on December 31 of the same year.

By exception, the first fiscal year shall end on December 31, 1991.

ARTICLE 8 - ALLOCATION OF THE PROFITS

If the results of the fiscal year, as approved by the general shareholders meeting, show the existence of a distributable profit, the general shareholders meeting shall decide to allocate such profit to one or several reserve accounts of which the general shareholders meeting decides the attribution or use, to carry it forward or to distribute it.

After acknowledging the existence of reserves, the general shareholders meeting may decide the distribution of the amounts taken from the reserves. In this case, the decision expressly mentions the reserve accounts from which the amounts are taken. The general shareholders meeting may also grant to each shareholder, an option between the payment in cash or in shares of all or part of the paid dividend.

ARTICLE 9 - TYPE OF THE SHARES

The shares are registered.

They shall be registered on an account opened by the Company in the name of the shareholder under the conditions set forth in applicable law and regulations. An affidavit of inscription on the account can be granted to the shareholder on shareholder’s request.

ARTICLE 10 – SALE AND ASSIGNMENT OF SHARES

Shares are freely negotiable under the conditions and limitations set forth by applicable law and regulations.

Any transfer of shares takes place, as far as both the Company and third parties are concerned, by way of transfer order signed by the assignor or its representative and the assignee if the shares have not yet been paid-up. The transfer order is registered on the day of its receipt on a numbered and initialized register called "*registre des mouvements*" (share transfer ledger).

The Company may require that the signatures on the transfer orders be certified by a public officer or a mayor, without prejudice to any legal rules to the contrary.

Shares transfer fees are borne by the assignee, except agreement to the contrary between the parties.

Transfer orders concerning shares not paid up to amounts due and payable shall be rejected.

The Company updates, at least on a six-month basis, the list of shareholders with the indication of the domicile declared by the shareholders.

Title to the shares results from their inscription in the name of the holder(s) on the registers or accounts held to that end by the Company or its representative.

ARTICLE 11 – RIGHTS AND DUTIES ATTACHED TO THE SHARES

Each share gives the right to title in the Company's assets, a share in profit and in the liquidation surplus, proportional to the value of the existing shares.

The same treatment shall be applied to all the shares that make up or that shall re make up the share capital, as far as the fiscal expenses are concerned.

As a consequence, all taxes that, for any reason, due to the repayment of the capital of these shares, could become due with respect to certain of them only, either during the life of the Company or upon liquidation thereof, shall be allocated among all the shares composing the capital at the moment of this repayment or these repayments, such that all existing or future shares grant to their holder, for the paid-up but not redeemed amount, the same real benefits and give them the right to receive the same net proceeds.

Each time it is necessary to hold several shares to exercise any right, the isolated shares or shares in an number less than the one required number, shall give no right to their holders against the Company; the shareholders shall, in this case, be personally responsible for the gathering of the necessary number of shares.

ARTICLE 12 – PAYMENT OF THE SHARE CAPITAL

The amounts that remain to be paid on the shares to be paid in cash are requested by the board of directors.

The shareholders are informed of the amounts requested and of the date when the corresponding amounts must be paid, either by a newspapers notice inserted fifteen days in advance in a journal authorized to publish legal notices in the department where the registered office is located, or by registered letter sent to each of the shareholders within the same time period.

A shareholder that does not proceed on time with the requested payments on the shares he holds, shall automatically and without prior notice owe a late payment interest calculated day by day, as of the date the amount was due, at the legal rate applicable in commercial matters plus tree points and without prejudice to enforcement measures set forth by law.

ARTICLE 13 – BOARD OF DIRECTORS

The Company is managed by a Board of Directors composed of at least three members and a maximum of eighteen members.

Subject to the decisions for which French law requires the physical presence of the Directors, the Board of Directors may provide for in its internal regulation that Directors who participate in the board meeting via videoconferencing or telecommunications means allowing for their identification and guaranteeing their effective participation in the Board meeting, in accordance with the provisions of a *Conseil d'Etat* decree, are deemed present for calculation of the quorum and the majority.

During the term of the Company, the members of the Board of Directors are appointed and removed, in the conditions provided by applicable laws and regulations.

Each member of the Board of Directors must own at least one share during the whole term of his/her office.

The term of office of the members of the Board of Directors is one year. It expires at the end of the shareholders' meeting called on to rule on the financial statements for the last financial year.

The number of Directors being over the age of 70 years may not, at any time, exceed one third of the total number of Directors in office.

ARTICLE 14 - DELIBERATIONS OF THE BOARD OF DIRECTORS

Board Meetings are convened by the Chairman, as frequently as the interests of the Company so require, either at the registered office, or in any other place indicated in the convening notice.

The members of the Board are convened to meetings by any means, even verbally.

When the Board of Directors has not met for more than two months, at least one third of the members of the Board may request the Chairman to convene a meeting for a defined agenda.

The Managing Director may also request the Chairman to convene a meeting for a defined agenda.

The Chairman is bound by the requests that are addressed to him pursuant to these last two paragraphs.

For sake of validity of deliberations, the effective attendance of at least half of the members in office is required.

Decisions are made with the majority of members present or duly represented: each member holds one vote, and each member may only hold one proxy. The Chairman has no tie-breaking vote.

Deliberations of the Board are recorded in minutes drawn-up, signed and recorded in accordance with applicable laws and regulations.

Copies and excerpts of the minutes for producing in court or elsewhere shall be validly certified either in accordance with applicable laws and regulations.

ARTICLE 15 – POWERS OF THE BOARD OF DIRECTORS

The Board determines the orientation of the Company's activity and ensures that they are implemented. Subject to the powers expressly granted to the Shareholders Meetings and within the corporate purpose, the Board may address any issue relating to the good operation of the Company and settles Company business through its deliberations.

In its relations to third parties, the Company is bound even by the actions of the Board of Directors that are unrelated to the corporate purpose, unless it can prove that the third party knew that the action exceeded the purpose or could not ignore it under the circumstances, it being excluded that the publication of the by-laws alone is sufficient to constitute such proof.

The Board of Directors undertakes the checks and verifications that it considers to be appropriate. Each Director receives all the information necessary to accomplish his mission and has access to all documents that he considers useful.

ARTICLE 16 – CHAIRMAN OF THE BOARD OF DIRECTORS

The Board of Directors elects from amongst its members a Chairman, who must be an individual. The Board determines the Chairman's term of office, which may not exceed his term of office as a Director.

The Chairman of the Board of Directors represents the Board vis-à-vis shareholders and third parties. He organizes and manages the work of the Board and reports thereon to the meeting of the shareholders. He oversees the good operation of the Company bodies, in accordance with applicable laws and regulations.

The Chairman of the Board may simultaneously hold offices of managing directors, member of a Board of Directors, of sole managing director, or member of a supervisory Board of stock corporations (*sociétés anonymes*) having their registered office in the French territory, only to the extent permitted by applicable laws and regulations

The Chairman of the Board is re-eligible. The Board of Directors may remove him/her at any time.

ARTICLE 17 – GENERAL MANAGEMENT

The general management of the Company is carried out, under his responsibility, either by the Chairman of the Board of Directors or by any other individual appointed by the Board, whether or not chosen from amongst its members, and having the title of Managing Director (*Directeur Général*).

The Board of Directors chooses between these two ways of exercising the General Management by a simple majority vote. Absent a vote to that effect, general management is undertaken by the Chairman of the Board of Directors, until a contrary decision is adopted by the Board of Directors.

When the general management of the Company is undertaken by the Chairman of the Board of Directors, the provisions of these by-laws relating to the Managing Director apply to the Chairman of the Board.

The Managing Director is appointed for a term of one year, expiring at the end of the general shareholders' meeting called on to rule on the approval of the financial statements for the last financial year.

The Managing Director has the most extensive powers to act under all circumstances in the name of the Company. He exercises these powers within the limit of the corporate purpose and subject to the powers expressly granted by law to Board and Shareholder meetings.

He represents the Company in its relations with third parties. The Company is even bound by the actions of the Managing Director that are not within the scope of the corporate purpose, unless it can prove that the third party knew that the action exceeded this purpose or could not ignore this fact under the circumstances, it being excluded that the publication of the by-laws alone is sufficient to constitute such proof.

The provisions of these by-laws and the decisions of the Board of Directors limiting the powers of the Managing Director may not be invoked against third parties.

Upon a proposal by the Managing Director, the Board of Directors may appoint one or several individuals with the title of Executive Managing Director, responsible for assisting the Managing Director. The Board of Directors may not appoint more than five Executive Managing Directors.

Executive Managing Directors have the same powers as the Managing Director in respect of third parties. With the Managing Director's approval, the Board of Directors determines the extent and duration of the powers assigned to the Executive Managing Directors.

The Board of Directors may remove the Managing Director at any time. The Executive Managing Directors may also be removed, upon a proposal of the Managing Director. If the removal is without just cause, it may give rise to damages, unless the Managing Director also assumes the functions of the Chairman of the Board of Directors.

Whenever the Managing Director ceases to carry or is prevented from carrying out his duties, the Executive Managing Directors retain their duties and attributions, subject to a contrary decision by the Board, until a new Managing Director is appointed.

An individual may not hold more than one office of Managing Director of stock corporations (*sociétés anonymes*) having their registered office on the French territory.

The remuneration of the Chairman, and that of the Managing Director and Executive Managing Directors, is determined by the Board of Directors; it may be fixed or proportional or both.

ARTICLE 18 – STATUTORY AUDITORS

The control of the Company's financial statements is carried out by one or several statutory auditors, appointed and exercising their duties, in the conditions provided by law.

The statutory auditor(s) may be assisted with one or several controllers appointed by the Board of Directors and chosen either from amongst its members, or from outside them. The controllers may be invited by the Chairman to attend to meetings of the Board of Directors. In this case, they have a consultative vote.

ARTICLE 19 – GENERAL MEETINGS OF SHAREHOLDERS

Shareholders' meetings are called in the conditions provided by applicable laws and regulations.

Meetings take place at the registered office or at any other place indicated in the calling notice.

The right to participate in shareholders' meetings is subject to:

- the registration of the shareholder in the Company's share accounts for owners of registered shares,
- the deposit, at the place indicated in the calling notice, of a certificate of account registration issued by the bank, the financial establishment or the stockbroker, depositary of the shares, as the case may be, for the owners of bearer shares.

The time period during which these formalities must be completed expires a day before the date of the meeting.

General meetings of shareholders are chaired by the Chairman of the Board of Directors, or, in his/her absence, by a director specially delegated to this end by the Board, failing which the shareholders' meeting elects its chairman.

The duties of scrutineers are fulfilled by two members of the meeting present and accepting, who hold the higher number of shares.

The meeting officials appoint the secretary of the meeting, who may choose from outside the shareholders.

An attendance sheet is drawn up in the conditions provided by applicable laws and regulations.

Are deemed to be present for purposes of calculating the quorum and majority, the shareholders who participate in the meeting by videoconference or by means of telecommunication, the nature and conditions of which are determined by a Decree issued by the *Conseil d'Etat* .

The copies and excerpts of the minutes of the shareholders' meeting are validly certified in accordance with the conditions provided by applicable laws and regulations.

ARTICLE 20 – POWERS AND RESOLUTIONS OF THE SHAREHOLDERS' MEETINGS

The ordinary and extraordinary shareholders' meetings, ruling under the conditions of quorum and majority prescribed by provisions respectively governing them, exercise the powers granted to them by applicable laws and regulations.

ARTICLE 21 - DISSOLUTION - LIQUIDATION

Upon expiration of the term of the Company or in the event of earlier dissolution, the shareholders' meeting determines the method of liquidation and appoints one or several liquidators, of whom it determines their powers, and who exercise their duties in accordance with applicable laws and regulations.

ARTICLE 22 - DISPUTES

Any dispute that may arise during the existence or liquidation of the Company, either between the shareholders or between the Company and the shareholders, regarding the interpretation or the enforceability of these by-laws or regarding, generally, any corporate matter, will be submitted to the relevant courts having jurisdiction where the registered office is located.

To that effect, in the event of a dispute, every shareholder must elect domicile in a place where the courts have jurisdiction over the registered office and all summons or services of process are validly delivered to this domicile.

CERTIFIED TRUE COPY

Exhibit 4.7

FACILITY AGREEMENT

FACILITY AGREEMENT (this "Agreement"), dated as of December 31, 2012, between Flamel US Holdings Inc., a Delaware Corporation (the "Borrower"), and the lenders set forth on Schedule 1 attached hereto (the "Lenders" and, together with the Borrower, the "Parties").

WITNESSETH:

WHEREAS, the Borrower wishes to borrow from the Lenders fifteen million Dollars ($15,000,000) for the purpose described in Section 2.1; and

WHEREAS, the Lenders desire to make, loans to the Borrower for such purpose,

NOW, THEREFORE, in consideration of the mutual agreements set forth herein, the Parties agree as follows:

ARTICLE 1

DEFINITIONS

Section 1.1 General Definitions. Wherever used in this Agreement, the Exhibits or the Schedules attached hereto, unless the context otherwise requires, the following terms have the following meanings:

"Affiliate" means, with respect to any Person, any other Person:

(a) that owns, directly or indirectly, in the aggregate more than 10% of the beneficial ownership interest of such Person;

(b) that directly or indirectly through one or more intermediaries controls, or is controlled by, or is under common control with, such Person; or

(c) that directly or indirectly is a general partner, controlling shareholder, or managing member of such Person.

"Applicable Laws" means all statutes, rules and regulations of the U.S. Food and Drug Administration ("FDA") and of other Governmental Authorities in the United States or elsewhere exercising regulatory authority similar to that of the FDA applicable to the ownership, testing, development, manufacture, packaging, processing, use, distribution, marketing, labeling, promotion, sale, offer for sale, storage, import, export or disposal of any product manufactured or distributed by or on behalf of the Borrower or its Subsidiaries.

"Authorizations" has the meaning set forth in Section 3.1(p).

"SEC Reports" means the annual, quarterly and periodic reports filed by SA with the SEC.

"Business Day" means a day on which banks are open for business in The City of New York.

"Coreg Receivables" has the meaning set forth in Exhibit B hereto.

"Code" means the Internal Revenue Code of 1986, as amended, and any Treasury Regulations promulgated thereunder.

"Default" means any event which, at the giving of notice, lapse of time or fulfillment of any other applicable condition (or any combination of the foregoing), would constitute an Event of Default.

"Disbursement" and "Disbursement Date" have the meaning given to it in Section 2.2.

"Dollars" and the "$" sign mean the lawful currency of the United States of America.

"Event of Default" has the meaning given to it in Section 5.4.

"Exchange Act" means the Securities Exchange Act of 1934, as amended, including the rules and regulations promulgated thereunder.

"Excluded Taxes" means with respect to any Lender, (a) income or franchise Taxes imposed on (or measured by) such Lender's net income by the United States of America, or by the jurisdiction (or any political subdivision thereof) under the laws of which such Lender is organized or incorporated or in which the applicable lending office of such Lender is located, (b) any branch profits Taxes imposed by the United States of America, or (c) any withholding Tax that is imposed on amounts payable to the Lender at the time the Lender becomes a party to this Agreement (or designates a new lending office) or is directly attributable to such Lender's failure or inability to comply with Section 2.5(d), except to the extent that the Lender (or its assignor, if any) was entitled, at the time of designation of a new lending office (or assignment), to receive additional amounts from the Borrower with respect to such withholding Tax pursuant to Section 2.5(a) or is legally unable to comply with Section 2.5(d) as a result of any change in the laws of the United States of America, the British Virgin Islands or France occurring subsequent to the date such Lender becomes a party to this Agreement (or designates a new lending office).

"Final Payment" means such amount as may be necessary to repay the outstanding principal amount of the Notes and any other amounts owing by the Borrower to the Lenders pursuant to the Transaction Documents.

"Final Payment Date" means the earlier of (i) the date on which the Borrower repays the Notes (together with any other amounts accrued and unpaid under the Transaction Documents) and (ii) the fourth anniversary of the date hereof.

"GAAP" means generally accepted accounting principles consistently applied as set forth in the opinions and pronouncements of the Accounting Principles Board and the American Institute of Certified Public Accountants and statements and pronouncements of the Financial Accounting Standards Board (or agencies with similar functions of comparable stature and authority within the accounting profession).

"Government Authority" means any government, governmental department, ministry, cabinet, commission, board, bureau, agency, tribunal, regulatory authority, instrumentality, judicial, legislative, fiscal, or administrative body or entity, whether domestic or foreign, federal, state or local, having jurisdiction over the matter or matters and Person or Persons in question.

"Guaranties" means the Guaranty by SA and affiliates of Flamel US Holdings Inc. for the benefit of the (i) Lenders of the obligations of the Borrower under this Agreement (the "FA Guaranty")and (ii) Buyers (as defined in the Royalty Agreement)of the obligations of the Payor under the Royalty Agreement (the "RA Guaranty").

"Hedging Obligations" means all liabilities under take-or-pay or similar arrangements or under any interest rate swaps, caps, floors, collars and other interest hedge or protection agreements, treasury locks, equity forward contracts, currency agreements or commodity purchase or option agreements or other interest or exchange rate or commodity price hedging agreements and any other derivative instruments, in each case, whether the Borrower and its Subsidiaries is liable contingently or otherwise, as obligor, guarantor or otherwise, or in respect of which liabilities the Borrower or its Subsidiaries otherwise assures a creditor against loss.

"Indebtedness" means the following:

(i) all indebtedness for borrowed money;

(ii) the deferred purchase price of assets or services (other than payables) which in accordance with GAAP would be shown to be a liability (or on the liability side of a balance sheet);

(iii) all guarantees of Indebtedness;

(iv) the maximum amount of all letters of credit issued or acceptance facilities established for the account of the Borrower and any of its Subsidiaries, including without duplication, all drafts drawn thereunder;

(v) all capitalized lease obligations;

(vi) all indebtedness of another Person secured by any Lien on any property of the Borrower or its Subsidiaries, whether or not such indebtedness has been assumed or is recourse (with the amount thereof, in the case of any such indebtedness that has not been assumed by the Borrower or its Subsidiaries, being measured as the lower of (x) fair market value of such property and (y) the amount of the indebtedness secured);

(vii) all Hedging Obligations; and

(viii) indebtedness created or arising under any conditional sale or title retention agreement.

"Indemnified Person" has the meaning given to it in Section 6.11.

"Indemnified Taxes" means all Taxes including Other Taxes, other than Excluded Taxes.

"Indemnity" has the meaning given to it in Section 6.11.

"Interest Rate" means 12.5% simple interest per annum.

"IP" and "Intellectual Property" have the meaning given to it in Section 3.1(l).

"Lien" means any lien, pledge, preferential arrangement, mortgage, security interest, deed of trust, charge, assignment, hypothecation, title retention, privilege or other encumbrance on or with respect to property or interest in property.

"Loan" means the loan made available by the Lenders to the Borrower pursuant to Section 2.2 in the amount of fifteen million Dollars ($15,000,000) or, as the context may require, the principal amount thereof from time to time outstanding.

"Loss" has the meaning given to it in Section 6.11.

"Material Adverse Effect" means a material adverse effect on the business, operations, condition (financial or otherwise) or assets of the Borrower and its Subsidiaries, taken as a whole.

"Notes" means the Notes issued to the Lenders evidencing the Loan in the form attached hereto as Exhibit B.

"Obligations" means all obligations (monetary or otherwise) of the Borrower arising under or in connection with the Transaction Documents.

"Organizational Documents" means the documents under which the Borrower was organized, each as amended to date, of this Agreement.

"Other Taxes" means any and all present or future stamp or documentary taxes or any other excise or property taxes, duties, other charges or similar levies, and all liabilities with respect thereto, together with any interest, fees, additions to tax or penalties applicable thereto (including by reason of any delay in payment) arising from any payment made hereunder or from the execution, delivery, registration or enforcement of, or otherwise with respect to, any Transaction Document.

"Permitted Indebtedness" means:

(i) The Obligations;

(ii) Item (ii) (including any earnout and other similar obligations incurred to a seller in an acquisition) under the definition of Indebtedness;

(iii) Item (v) under the definition of Indebtedness;

(iv) Indebtedness secured by purchase money Liens; provided that such Indebtedness when incurred by the Borrower or any of its Subsidiaries shall not exceed the purchase price of the asset(s) financed;

(v) Indebtedness of any Person acquired pursuant to an acquisition, provided that such Indebtedness is either (i) not incurred in contemplation of or in connection with such acquisition or (ii) constitutes Indebtedness owing to the seller of the assets acquired in such acquisition;

(vi) Indebtedness existing as of the date hereof and set forth on Exhibit C attached hereto;

(vii) [Reserved].

(viii) Hedging Obligations incurred in the ordinary course of business not for speculative purposes;

(ix) Indebtedness for borrowed money subordinated to the Notes by documentation that is reasonably acceptable to the Borrower in form and content;

(x) Indebtedness in respect of letters of credit in an aggregate outstanding amount not to exceed $750,000 at any time;

(xi) Performance bonds, surety bonds, bank guaranties and similar instruments incurred in the ordinary course of business;

(xii) Guarantees with respect to any Permitted Indebtedness;

(xiii) [Reserved];

(xiv) Indebtedness in an aggregate amount outstanding at any time of not more than $15,000,000 that is subordinated in right of payment to the Notes pursuant to a Subordination Agreement satisfactory in form and content to the Lenders;

(xv) Indebtedness in an aggregate amount of 15,000,000 Euros outstanding at any one time from a Government Authority of The Republic of France;

(xvi) Indebtedness incurred to pay the promissory note provided for in Section 2(j) of the Warrants;

(xvii) Indebtedness incurred to purchase equipment; and

(xviii) Any refinancings, renewals, extensions, increases or replacements of Indebtedness listed in clauses (ii), (iii), (iv) and (v) so long as no such Indebtedness shall be refinanced for a principal amount in excess of the principal balance outstanding thereon at the time of such refinancing.

"Permitted Liens" means:

(i) Liens existing on the date hereof and set forth on Exhibit D attached hereto, and any renewals or extensions thereof, provided that the property covered thereby is not increased and any renewal or extension of the obligations secured or benefited thereby is permitted by clause (iii), (iv) or (vi) of the definition of Permitted Indebtedness;

(ii) Liens in favor of the Lenders;

(iii) Statutory Liens created by operation of applicable law;

(iv) Liens arising in the ordinary course of business and securing obligations that are not more than 30 days past due or are being contested in good faith by appropriate proceedings;

(v) Liens for taxes, assessments or governmental charges or levies not more than 30 days past due and payable or that are being contested in good faith by appropriate proceedings;

(vi) Liens arising from judgments, decrees or attachments in circumstances not constituting an Event of Default;

(vii) Liens in favor of financial institutions arising in connection with the Borrower's or its Subsidiaries' accounts maintained in the ordinary course of the Borrower's and its Subsidiaries' business held at such institutions to secure standard fees for services charged by, but not financing made available by, such institutions;

(viii) Liens securing Indebtedness permitted pursuant to clauses (iii), (iv) and (v) of the definition of Permitted Indebtedness;

(ix) Lessor liens;

(x) Pledges or deposits in the ordinary course of business in connection with workers' compensation, unemployment insurance and other social security legislation;

(xi) Deposits to secure (i) the performance of tenders, bids, trade contracts, licenses and leases, statutory obligations, surety bonds, performance bonds, bank guaranties and other obligations of a like nature incurred in the ordinary course of business (including earnest money deposits in respect of any acquisition), or (ii) indemnification obligations relating to any disposition;

(xii) Easements, rights of way, restrictions and other similar encumbrances affecting real property which, in the aggregate, are not substantial in amount, and which do not in any case materially interfere with the ordinary conduct of the business of the applicable Person;

(xiii) Leases, licenses or subleases granted to others not interfering in any material respect with the business of the Borrower and its Subsidiaries;

(xiv) Liens of a collection bank arising under Section 4-210 of the Uniform Commercial Code (or equivalent in foreign jurisdictions) on items in the course of collection;

(xv) Licenses of intellectual property granted by the Borrower or any of its Subsidiaries in the ordinary course of business and not interfering in any material respect with the ordinary conduct of business of the Borrower and its Subsidiaries;

(xvi) Good faith deposits required in connection with any acquisition;

(xvii) To the extent constituting a Lien, escrow arrangements securing indemnification obligations associated with any acquisition;

(xviii) Liens (i) on advances of cash or cash equivalents in favor of the seller of any property to be acquired by the Borrower or any of its Subsidiaries to be applied against the purchase price for such acquisition; provided, that (x) the aggregate amount of such advances of cash or cash equivalents shall not exceed the purchase price of such acquisition and (y) the property is acquired within 90 days following the date of the first such advance so made; and (ii) consisting of an agreement to dispose of any property in a disposition of assets, in each case, solely to the extent such acquisition or disposition, as the case may be, would have been permitted on the date of the creation of such Lien;

(xix) Liens on cash collateral securing reimbursement obligations of the Borrower and its Subsidiaries under letters of credit;

(xx) Liens not otherwise permitted hereunder in respect of obligations in an aggregate amount not to exceed $500,000 at any time outstanding.

"Person" means and includes any natural person, individual, partnership, joint venture, corporation, trust, limited liability company, limited company, joint stock company, unincorporated organization, government entity or any political subdivision or agency thereof, or any other entity.

"Register" has the meaning set forth in Section 1.4.

"Royalty Agreement" means that certain Royalty Agreement in the form attached hereto as Exhibit E.

"SA" means Flamel Technologies SA

"SEC" means the United States Securities and Exchange Commission.

"Securities Act" means the Securities Act of 1933, as amended, including the rules and regulations promulgated thereunder.

"Security Agreements" mean (A) agreements governed by the laws of France pursuant to which (i) SA grants to the Lenders a lien on its property, plant and equipment located in Pessac, France to secure its obligations under its FA Guaranty and its RA Guaranty (the "Flamel FA/RA Guaranties")and (ii) SA grants to the Buyers a lien on the Coreg Receivables to secure its obligations under the Flamel FA/RA Guaranties and (B) an agreement governed by the laws of New York pursuant to which Eclat Pharmaceuticals, LLC grants to the Buyers (as defined in the Royalty Agreement) a lien on its Product Regulatory Rights and its Proprietary Rights (as such terms are defined in the Royalty Agreement) to secure its obligations under the Royalty Agreement.

"Subsidiary or Subsidiaries" means, as to the Borrower, any entity of which securities or other ownership interests having ordinary voting power to elect a majority of the board of directors or other persons performing similar functions are at the time directly or indirectly owned by the Borrower.

"Taxes" means all present or future taxes, levies, imposts, stamp or other duties, fees, assessments, deductions, withholdings, all other governmental charges, and all liabilities with respect thereto, together with any interest, fees, additions to tax or penalties applicable thereto (including by reason of any delay in payment).

"Transaction Documents" means this Agreement, the Notes, the Security Agreements, the Guaranties, the Royalty Agreement and any other document or instrument delivered in connection with any of the foregoing and dated the date of this Agreement or subsequent to such date, whether or not specifically mentioned herein or therein.

"Warrants" mean the Warrants issued by the Borrower pursuant to that certain Membership Interest Purchase Agreement made and entered into as of March 13, 2012, by and among Eclat Holdings, LLC, Eclat Pharmaceuticals, LLC, SA and the Borrower.

Section 1.2 Interpretation. In this Agreement, unless the context otherwise requires, all words and personal pronouns relating thereto shall be read and construed as the number and gender of the party or parties requires and the verb shall be read and construed as agreeing with the required word and pronoun; the division of this Agreement into Articles and Sections and the use of headings and captions is for convenience of reference only and shall not modify or affect the interpretation or construction of this Agreement or any of its provisions; the words "herein," "hereof," "hereunder," "hereinafter" and "hereto" and words of similar import refer to this Agreement as a whole and not to any particular Article or Section hereof; the words "include," "including," and derivations thereof shall be deemed to have the phrase "without limitation" attached thereto unless otherwise expressly stated; references to a specified Article, Exhibit, Section or Schedule shall be construed as a reference to that specified Article, Exhibit, Section or Schedule of this Agreement; and any reference to any of the Transaction Documents means such document as the same shall be amended, supplemented or modified and from time to time in effect.

Section 1.3 **Business Day Adjustment.** If the day by which a payment is due to be made is not a Business Day, that payment shall be made by the next succeeding Business Day unless that next succeeding Business Day falls in a different calendar month, in which case that payment shall be made by the Business Day immediately preceding the day by which such payment is due to be made.

Section 1.4

(a) The Borrower shall record on its books and records the amount of the Loan, the interest rate applicable, all payments of principal and interest thereon and the principal balance thereof from time to time outstanding. Such record shall, absent manifest error, be conclusive evidence of the amount of the Loan made by the Lenders to the Borrower and the interest and payments thereon.

(b) The Borrower shall establish and maintain at its address referred to in Section 6.1, a record of ownership (the "Register") in which the Borrower agrees to register by book entry the interests (including any rights to receive payment hereunder) of each Lender in the Loan, and any assignment of any such interest, and (ii) accounts in the Register in accordance with its usual practice in which it shall record (1) the names and addresses of the Lenders (and any change thereto pursuant to this Agreement), (2) the amount of the Loan and each funding of any participation therein, (3) the amount of any principal or interest due and payable or paid, and (4) any other payment received by the Lenders from the Borrower and its application to the Loan.

(c) Notwithstanding anything to the contrary contained in this Agreement, the Loan (including any Notes evidencing the Loan) is a registered obligation, the right, title and interest of the Lenders and their assignees in and to the Loan shall be transferable only upon notation of such transfer in the Register and no assignment thereof shall be effective until recorded therein. This Section 1.4 shall be construed so that the Loan is at all times maintained in "registered form" within the meaning of Sections 163(f), 871(h)(2) and 881(c)(2) of the Code.

(d) The Borrower and the Lenders shall treat each Person whose name is recorded in the Register as a Lender for all purposes of this Agreement. Information contained in the Register with respect to any Lender shall be available for access by the Borrower or such Lender at any reasonable time and from time to time upon reasonable prior notice.

ARTICLE 2

AGREEMENT FOR THE LOAN

Section 2.1 **Use of Proceeds.** The proceeds of the Loan will be used for working capital without limitation as to its use, except as otherwise prohibited by the Transaction Documents.

Section 2.2 Disbursement. Subject to satisfaction of the conditions contained in Article 4, the Loan shall be made (the "Disbursement") on such date as the Borrower and the Lenders shall determine (the "Disbursement Date"). The Lenders shall effect the Disbursement on the Disbursement Date in accordance with their respective allocations set forth on Schedule 1. The Borrower's wire instructions for its account located in the United States are attached as Schedule 2.

Section 2.3 Payment. (a) The Borrower shall remit the Final Payment to the Lenders on the earlier to occur of (i) the Final Payment Date and (ii) the date the principal amount of the Notes is declared to be or automatically becomes due and payable following an Event of Default. Purchaser shall remit to the Lenders 10%, 20%, 30%, and 40%, respectively, of the original aggregate principal amount of the Notes on July 1, 2014 and the second, third and fourth anniversaries, respectively, of the Disbursement Date.

(a) The Notes may be prepaid in whole or in part on any Interest Payment Date after the first anniversary of the date of this Agreement, together with interest due on such date, without any premium or penalty and may not be prepaid prior to such date. Each prepayment shall be applied first, to accrued and unpaid interest and second, to principal and shall be allocated among the Lenders in accordance with their respective allocations set forth on Schedule 1.

Section 2.4 Payments. Payments of any amounts due to the Lenders under this Agreement shall be made in Dollars in immediately available funds prior to 11:00 a.m New York City time on such date that any such payment is due, at such bank or places as the Lenders shall from time to time designate in writing at least 5 Business Days prior to the date such payment is due. The Borrower shall pay all and any costs (administrative or otherwise) imposed by banks, clearing houses, or any other financial institution, in connection with making any payments under any of the Transaction Documents, except for any costs imposed by the Lenders' banking institutions.

Section 2.5 Taxes, Duties and Fees.

(a) Any and all payments hereunder or under any other Transaction Document shall be made, in accordance with this Section 2.5, free and clear of and without deduction for any and all present or future Indemnified Taxes except as required by applicable law. If Borrower shall be required by law to deduct any Indemnified Taxes from or in respect of any sum payable hereunder or under any other Transaction Document, (i) the sum payable shall be increased by as much as shall be necessary so that after making all required deductions (including deductions applicable to additional sums payable under this Section 2.5) the Lenders shall receive an amount equal to the sum they would have received had no such deductions been made (any and all such additional amounts payable to Lenders shall hereafter be referred to as the "Additional Amounts"), (ii) Borrower shall make such deductions, and (iii) Borrower shall pay the full amount deducted to the relevant taxing or other authority in accordance with applicable law. Within thirty (30) days after the date of any payment of such Taxes, Borrower shall furnish to the applicable Lender the original or a certified copy of a receipt evidencing payment thereof or other evidence of such payment reasonably satisfactory to such Lender.

(b) In addition, Borrower agrees to pay, and authorizes Lenders to pay in its name, all Other Taxes. Within 30 days after the date of any payment of Other Taxes, Borrower shall furnish to Lenders the original or a certified copy of a receipt evidencing payment thereof or other evidence of such payment reasonably satisfactory to Lenders.

(c) Borrower shall reimburse and indemnify, within 10 days after receipt of demand therefor, each Lender for all Indemnified Taxes (including all Taxes and Other Taxes imposed by any jurisdiction on amounts payable under this Section 2.5(c)) paid by such Lender, whether or not such Indemnified Taxes were correctly or legally asserted. A certificate of the applicable Lender(s) setting forth the amounts to be paid thereunder and delivered to Borrower shall be conclusive, binding and final for all purposes, absent manifest error.

(d) Each Lender (other than a Foreign Person (as hereinafter defined)) on or before the date hereof shall provide to Borrower a properly completed and executed IRS Form W-9 certifying that such Lender is organized under the laws of the United States. Each Lender organized under the laws of a jurisdiction outside the United States (a "Foreign Person") that is entitled to an exemption from or reduction in U.S. withholding tax shall provide Borrower with a properly completed and executed IRS Form W-8ECI, W-8BEN, W-8IMY or other applicable form, or any other applicable certificate or document reasonably requested by the Borrower, and, if such Foreign Person that is relying on the portfolio interest exception of Section 871(h) or Section 881(c) of the Code (or any successor provision thereto), shall also provide the Borrower with a certificate (the "Portfolio Interest Certificate") representing that such Foreign Person is not a "bank" for purposes of Section 881(c) of the Code (or any successor provision thereto), is not a 10% holder of the Borrower described in Section 871(h)(3)(B) of the Code (or any successor provision thereto), is not a controlled foreign corporation receiving interest from a related person (within the meaning of Sections 881(c)(3)(C) and 864(d)(4) of the Code, or any successor provisions thereto) and is not a conduit entity participating in a conduit Transaction arrangement as defined in Treasury Regulation Section 1.881-3 (or any successor provision thereto). Each Lender shall provide new forms (or successor forms) upon the expiration or obsolescence of any previously delivered forms and shall promptly notify the Borrower of any change in circumstances which would modify or render invalid any claimed exemption or reduction.

(e) If a Lender determines in good faith that it has received a refund from a Government Authority relating to Taxes in respect of which the Borrower paid Additional Amounts or made a payment pursuant to Section 2.5(c), such Lender shall promptly pay such refund to the Borrower, net of all out-of-pocket expense (including any Taxes imposed thereon) of such Lender incurred in obtaining such refund, provided that the Borrower, upon the request of such Lender, agrees to repay the amount paid over to the Borrower (plus any penalties, interest or other charges imposed by the relevant Governmental Authority) to such Lender if such Lender is required to repay such refund to such Governmental Authority. Nothing in this Section shall require any Lender to disclose any information it deems confidential (including, without limitation, its tax returns) to any Person, including Borrower.

Section 2.6 **Costs, Expenses and Losses.** If, as a result of any failure by the Borrower to pay any sums due under this Agreement on the due date therefor (after the expiration of any applicable grace periods), the Lenders shall incur costs, expenses and/or losses, by reason of the liquidation or redeployment of deposits from third parties or in connection with obtaining funds to make or maintain the Disbursement, the Borrower shall pay to the Lenders upon request by the Lenders, the amount of such costs, expenses and/or losses within fifteen (15) days after receipt by it of a certificate from the Lenders setting forth in reasonable detail such costs, expenses and/or losses, along with supporting documentation. For the purposes of the preceding sentence, "costs, expenses and/or losses" shall include, without limitation, any interest paid or payable to carry any unpaid amount and any loss, premium, penalty or expense which may be incurred in obtaining, liquidating or employing deposits of or borrowings from third parties in order to make, maintain or fund the Loan or any portion thereof.

Section 2.7 **Interest.** The outstanding principal amount of the Notes shall bear interest at the Interest Rate (calculated on the basis of the actual number of days elapsed in each month). Interest shall be paid quarterly in arrears commencing on April 1, 2013 and on the first Business Day of each July, October, January and April thereafter (each, an "Interest Payment Date").

Section 2.8 **Interest on Late Payments.** Without limiting the remedies available to the Lenders under the Transaction Documents or otherwise, to the maximum extent permitted by applicable law, if the Borrower fails to make a required payment of principal or interest with respect to the Loan when due the Borrower shall pay, in respect of such principal and interest at the rate per annum equal to the Interest Rate plus ten percent (10%) for so long as such payment remains outstanding. Such interest shall be payable on demand.

Section 2.9. **Fee and Costs** On the Disbursement Date, the Borrower shall pay to such entity as the Lenders shall direct a fee of $112,500 for entering into the transaction contemplated by the Transaction Documents and shall reimburse the Lenders of the legal costs and expense it incurred in effecting such transaction.

ARTICLE 3

REPRESENTATIONS AND WARRANTIES

Section 3.1 **Representations and Warranties of the Borrower.** The Borrower represents and warrants as of the date hereof that except as set forth in a Schedule to this Agreement or the SEC Reports for the year ended December 31, 2011 or the quarterly periods ended March 31, 2012, June 30, 2012 and September 30, 2012:

(a) The Borrower is conducting its business in compliance with its Organizational Documents, which are in full force and effect with no defaults outstanding thereunder.

(b) No Default or Event of Default (or any other default or event of default, however described) has occurred under any of the Transaction Documents.

(c) The Borrower (i) is capable of paying its debts as they fall due, is not unable and has not admitted its inability to pay its debts as they fall due, (ii) is not bankrupt or insolvent and (iii) has not taken action, and no such action has been taken by a third party, for the Borrower's winding up, dissolution, or liquidation or similar executory or judicial proceeding or for the appointment of a liquidator, custodian, receiver, trustee, administrator or other similar officer for the Borrower or any or all of its assets or revenues.

(d) No Lien exists on the Borrower's assets, except for Permitted Liens.

(e) The obligation of the Borrower to make any payment under this Agreement (together with all charges in connection therewith) is absolute and unconditional, and there exists no right of setoff or recoupment, counterclaim, cross-claim or defense of any nature whatsoever to any such payment.

(f) No Indebtedness of the Borrower exists other than Permitted Indebtedness.

(g) The Borrower is validly existing as a corporation in good standing under the laws of Delaware. The Borrower has full power and authority to own its properties and conduct its business, and is duly qualified to do business as a foreign entity and is in good standing in each jurisdiction in which the conduct of its business makes such qualification necessary and in which the failure to so qualify would not have a Material Adverse Effect.

(h) There is not pending or, to the knowledge of the Borrower, threatened, any action, suit or other proceeding before any Governmental Authority (a) to which the Borrower is a party or (b) which has as the subject thereof any assets owned by the Borrower. There are no current or, to the knowledge of the Borrower, pending, legal, governmental or regulatory enforcement actions, suits or other proceedings to which the Borrower or any of its assets is subject.

(i) The Transaction Documents have been duly authorized, executed and delivered by the Borrower, and constitute a valid, legal and binding obligation of the Borrower enforceable in accordance with its terms, except as such enforceability may be limited by applicable insolvency, bankruptcy, reorganization, moratorium or other similar laws affecting creditors' rights generally. The execution, delivery and performance of the Transaction Documents by the Borrower and the consummation of the transactions therein contemplated will not (A) conflict with or result in a breach or violation of any of the terms or provisions of, or constitute a default under, or result in the creation or imposition of any Lien upon any assets of the Borrower pursuant to, any agreement to which the Borrower is a party or by which the Borrower is bound or to which any of the assets of the Borrower is subject, (B) result in any violation of or conflict with the provisions of the Organizational Documents or (C) result in the violation of any law or any judgment, order, rule, regulation or decree of any Governmental Authority. No consent, approval, authorization or order of, or registration or filing with any Governmental Authority is required for the execution, delivery and performance of any of the Transaction Documents or for the consummation by the Borrower of the transactions contemplated hereby except filings contemplated with the Security Agreements and the Borrower has the corporate power and authority to enter into the Transaction Documents and to consummate the transactions contemplated under the Transaction Documents.

(j) The Borrower holds, and is operating in compliance in all material respects with, all franchises, grants, authorizations, licenses, permits, easements, consents, certificates and orders of any Governmental Authority (collectively, "Necessary Documents") required for the conduct of its business and all Necessary Documents are valid and in full force and effect; and the Borrower has not received written notice of any revocation or modification of any of the Necessary Documents and the Borrower has no reason to believe that any of the Necessary Documents will not be renewed in the ordinary course, and the Borrower is in compliance in all material respects with all applicable federal, state, local and foreign laws, regulations, orders and decrees applicable to the conduct of its business.

(k) The Borrower has good and marketable title to all of its assets free and clear of all Liens except Permitted Liens. The property held under lease by the Borrower is held under valid, subsisting and enforceable leases with only such exceptions with respect to any particular lease as do not interfere in any material respect with the conduct of the business of the Borrower.

(l) The Borrower owns or has the right to use pursuant to a valid and enforceable written license, implied license or other legally enforceable right, all of the Intellectual Property (as defined below) that is necessary for the conduct of its business as currently conducted (the "IP"). To the knowledge of the Borrower, the IP that is registered with or issued by a Governmental Authority is valid and enforceable; there is no outstanding, pending, or, to the knowledge of the Borrower, threatened action, suit, other proceeding or claim by any third person challenging or contesting the validity, scope, use, ownership, enforceability, or other rights of the Borrower in or to any IP and the Borrower has not received any written notice regarding, any such action, suit, or other proceeding. To the knowledge of the Borrower, the Borrower has not infringed or misappropriated any material rights of others. To the knowledge of the Borrower, there is no pending or threatened action, suit, other proceeding or claim by others that the Borrower infringes upon, violates or uses the Intellectual Property rights of others without authorization, and the Borrower has not received any written notice regarding, any such action, suit, other proceeding or claim. The Borrower is not a party to or bound by any options, licenses, or agreements with respect to IP. The term "Intellectual Property" as used herein means (i) all patents, patent applications, patent disclosures and inventions (whether patentable or unpatentable and whether or not reduced to practice), (ii) all trademarks, service marks, trade dress, trade names, slogans, logos, and corporate names and Internet domain names, together with all of the goodwill associated with each of the foregoing, (iii) copyrights, copyrightable works, and licenses, (iv) registrations and applications for registration for any of the foregoing, (v) computer software (including but not limited to source code and object code), data, databases, and documentation thereof, (vi) trade secrets and other confidential information, (vii) other intellectual property, and (viii) copies and tangible embodiments of the foregoing (in whatever form and medium).

(m) The Borrower is not in violation of the Organizational Documents, or in breach of or otherwise in default under, and no event has occurred which, with notice or lapse of time or both, would constitute such breach or other default in the performance of any agreement or condition contained in any agreement under which it may be bound, or to which any of its assets is subject, except for such breaches or defaults as would not have a Material Adverse Effect.

(n) The Borrower has timely filed, including pursuant to all extensions, all income and franchise tax returns required to be filed by any Governmental Authority (except where the failure to file would not have a Material Adverse Effect) and are not in default in the payment of any taxes which were payable pursuant to said returns or any assessments with respect thereto. There is no pending dispute with any taxing authority relating to any of such returns, and the Borrower has no knowledge of any proposed liability for any tax to be imposed upon its properties or assets.

(o) The Borrower has not granted rights to develop, manufacture, produce, assemble, distribute, license, market or sell its products to any other Person except in the ordinary course of business and is not bound by any agreement that affects the exclusive right of the Borrower to develop, manufacture, produce, assemble, distribute, license, market or sell its products except in the ordinary course of business

(p) The Borrower: (A) at all times has complied in all material respects with all Applicable Laws; (B) has not received any warning letter or other correspondence or notice from the FDA or any correspondence or notice from any other Governmental Authority alleging or asserting noncompliance with any Applicable Laws or any licenses, certificates, approvals, clearances, authorizations, permits and supplements or amendments thereto required by any Applicable Laws (together, the "Authorizations"); (C) possesses and complies in all material respects with the Authorizations, which are valid and in full force and effect; (D) has not received written notice that any Governmental Authority has taken, is taking or intends to take action to limit, suspend, modify or revoke any Authorization and have no knowledge that any Governmental Authority is considering such action; (E) has filed, obtained, maintained or submitted all reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any Applicable Laws or Authorizations, except as would not have a Material Adverse Effect; and (F) has not, either voluntarily or involuntarily, initiated, conducted, or issued or caused to be initiated, conducted or issued, any recall, market withdrawal or replacement, safety alert, post-sale warning, "dear doctor" letter, or other notice or action relating to the alleged lack of safety or efficacy of any product or any alleged product defect or violation and, to the Borrower's knowledge, no third party has initiated, conducted or intends to initiate any such notice or action.

(q) The studies, tests and preclinical and clinical trials conducted by or on behalf of the Borrower were and, if still pending, are being conducted in compliance in all material respects with experimental protocols, procedures and controls pursuant to accepted professional scientific standards and all Applicable Laws and Authorizations, including, without limitation, the Federal Food, Drug and Cosmetic Act and the rules and regulations promulgated thereunder; the Borrower is not aware of any studies, tests or trials, the results of which the Borrower believes reasonably call into question any of its studies, tests or trial results and the Borrower has not received any written notices or correspondence from any Governmental Authority requiring the termination, suspension, or material modification of any such studies, tests or preclinical or clinical trials.

(r) The financial statements of the Borrower provided to the Lenders prior to the Disbursement Dates and indentified as subject to this subsection (r) together with the related notes fairly present the financial condition of the Borrower as of the dates indicated and the results of operations and changes in cash flows for the periods therein specified in conformity with GAAP consistently applied throughout the periods involved, subject, in the case of unaudited financial statements, to year-end adjustments; and, except as disclosed in such Schedule, there are no material off-balance sheet arrangements or any other relationships with unconsolidated entities or other persons, that may have a material current or, to the Borrower's knowledge, material future effect on the Borrower's financial condition, results of operations, liquidity, capital expenditures, capital resources or significant components of revenue or expenses.

(s) The Borrower maintains a system of internal accounting controls sufficient to provide reasonable assurances that (i) transactions are executed in accordance with management's general or specific authorization; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain accountability for assets; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

(t) The Borrower has no Subsidiaries other than Eclat Pharmaceuticals LLC and its subsidiary, Talec LLC, a Delaware limited liability company.

(u) The Supply Agreement and the License Agreement (as such terms are defined in Exhibit B hereto) are the only material contracts relating to the subject matter of such agreements.

(v) The representations and warranties set forth in this Section 3.1 are applicable to the Borrower's Subsidiaries.

Section 3.2 Borrower Acknowledgment. The Borrower acknowledges that it has made the representations and warranties referred to in Section 3.1 with the intention of persuading the Lenders to enter into the Transaction Documents and that the Lenders have entered into the Transaction Documents on the basis of, and in full reliance on, each of such representations and warranties. The Borrower represents and warrants to the Lenders that none of such representations and warranties omits any matter the omission of which makes any of such representations and warranties misleading.

Section 3.3 Representations and Warranties of the Lenders. Each Lender represents and warrants to the Borrower as of the date hereof that:

(a) It is acquiring its Note for its account for investment, not as an agent or nominee, and not with a view to or for resale in connection with any distribution of the Notes.

(b) Its Note must be held indefinitely unless they are subsequently registered under the Securities Act or an exemption for such registration is available.

(c) Each Transaction Document to which it is a party has been duly authorized, executed and delivered by such Lender and constitutes its valid and legally binding obligation, enforceable in accordance with its terms, except as such enforceability may be limited by (i) applicable insolvency, bankruptcy, reorganization, moratorium or other similar laws affecting creditors' rights generally, and (ii) applicable equitable principles (whether considered in a proceeding at law or in equity).

ARTICLE 4

CONDITIONS OF DISBURSEMENT

Section 4.1 Conditions to the Disbursement. The obligation of the Lenders to make the Disbursement shall be subject to the fulfillment of the following conditions:

(a) The Lenders shall have received the payment contemplated by Section 2.9 and executed counterparts of the Guaranties, the Royalty Agreement and the Security Agreements in form generally accepted in the commercial community for transaction comparable to those contemplated by the Transaction Documents dated, except for this Agreement, the Disbursement Date, and as to the Borrower, a certificate as to its Organizational Documents, and resolutions and incumbency; and

(b) No Default or Event of Default has occurred or would result from the Disbursement.

ARTICLE 5

PARTICULAR COVENANTS AND EVENTS OF DEFAULT

Section 5.1 Affirmative Covenants. Unless the Lenders shall otherwise agree:

(i) The Borrower shall and shall cause its Subsidiaries to maintain its existence and qualify and remain qualified to do its business as currently conducted, except where the failure to so maintain such qualification would not reasonably be expected to have a Material Adverse Effect.

(ii) The Borrower shall and shall cause its Subsidiaries to comply in all material respects with all Applicable Laws, except where the necessity of compliance therewith is contested in good faith by appropriate proceedings or where the failure to comply would not have a Material Adverse Effect.

(iii) The Borrower shall obtain and shall cause its Subsidiaries to make and keep in full force and effect all licenses, certificates, approvals, registrations, clearances, authorizations and permits required to conduct their businesses, except where the failure to do so would not have a Material Adverse Effect.

(iv) The Borrower shall promptly notify the Lenders of the occurrence of (i) any Default or Event of Default and (ii) any claims, litigation, arbitration, mediation or administrative or regulatory proceedings that are instituted or threatened against the Borrower or any of its Subsidiaries that could reasonably be expected to have a Material Adverse Effect, and (iii) each event which, at the giving of notice, lapse of time, determination of materiality or fulfillment of any other applicable condition (or any combination of the foregoing), would constitute an event of default (however described) under any Transaction Document.

(v) (i) If SA is not required to file reports pursuant to the Exchange Act, the Borrower will cause SA to provide unaudited quarterly consolidated financial statements of SA and its Subsidiaries within 45 days after the end of each of the first three fiscal quarters of each calendar year, and audited annual consolidated financial statements of SA and its Subsidiaries within 120 days after the end of each calendar year prepared in accordance with GAAP (subject, in the case of unaudited financial statements, to the absence of footnotes and other presentation items and to normal year-end adjustments) with, in the case of annual financial statements, a report thereon by SA's independent certified public accountants, (ii) SA will timely file with the SEC (subject to appropriate extensions made under the Exchange Act) any annual reports, quarterly reports and other periodic reports required to be filed pursuant to the Exchange Act, and (iii) SA and its Subsidiaries will provide to the Lenders copies of all documents, reports, financial data and other information that the Lenders may reasonably request.

Section 5.2 Negative Covenants. Unless the Lenders holding a majority in interest of the Notes shall otherwise agree:

(i) The Borrower shall not and shall not permit any Subsidiary to (a) liquidate (other than Flamel Technologies Inc. which shall be promptly liquidated, and all proceeds thereof distributed to SA), provided that a Subsidiary may merge into the Borrower or any other Subsidiary, or dissolve (unless such Subsidiary ceases to own any operating assets or conduct business), or (b) enter into any merger, consolidation or reorganization, unless (x) the Borrower or a Subsidiary is the surviving corporation. The Borrower shall not maintain or establish any Subsidiary in the United States unless such Subsidiary executes and delivers to the Lenders a guarantee substantially in the form of the Guaranty if such Subsidiary is organized outside of the United States, in the form of a guaranty to the same effect as the Guaranty customary in the jurisdiction in which such Subsidiary is organized.

(ii) The Borrower shall not and shall not permit any Subsidiary to (i) enter into any partnership, joint venture, syndicate, pool, profit-sharing or royalty agreement or other combination, or engage in any transaction with an Affiliate, whereby its income or profits are, or might be, shared with another Person, (ii) enter into any management contract or similar arrangement whereby a substantial part of its business is managed by another Person, or (iii) distribute, or permit the distribution of, any of its assets, including its intangibles, to any shareholder of the Borrower or an Affiliate of such shareholder.

(iii) The Borrower shall not and shall not permit any Subsidiary to (a) create, incur or suffer any Lien upon any of its assets, now owned or hereafter acquired, except Permitted Liens or (b) assign, sell, transfer or otherwise dispose of, any Purchase Document, or the rights and obligations thereunder.

(iv) The Borrower shall not and shall not permit any Subsidiary to create, incur, assume, guarantee or remain liable with respect to any Indebtedness, other than Permitted Indebtedness.

(v) The Borrower shall not and shall not permit any Subsidiary to acquire any assets (other than assets acquired in the ordinary course of business consistent with past practices), directly or indirectly, in one or more related transaction, for a consideration, in cash or other property (valued at its fair market value) greater than $500,000.

No provision of this Agreement or any other Transaction Document shall be construed to prohibit the Borrower (or otherwise require the consent of the Lenders) from entering into bona fide business development transactions with Persons who are not Affiliates of the Borrower, which transactions may include exclusive licenses of Borrower's Intellectual Property to third party strategic partners.

Section 5.3 Major Transaction. The Borrower shall give the Lenders notice of the consummation of a Major Transaction involving SA (as such term is defined in the Warrants) on the shorter of 30 days prior to such consummation or 2 days following the public announcement thereof. Within 5 days after the receipt of such notice, the Lenders, in the exercise of their sole discretion, may deliver a notice to the Borrower (the "Put Notice"), that the Final Payment shall be due and payable upon consummation of such Major Transaction. If the Lenders deliver a Put Notice, then simultaneously with consummation of such Major Transaction, the Borrower shall make or cause to be made the Final Payment to the Lenders and upon the Lenders receipt of the Final Payment, the Obligations under this Agreement and the Notes. The Borrower shall take such steps as may be required to ensure that SA shall not consummate any Major Transaction until the Borrower complies with the provisions of this Section 5.3.

Section 5.4 General Acceleration Provision upon Events of Default. If one or more of the events specified in this Section 5.4 shall have happened and be continuing beyond the applicable cure period (each, an "Event of Default"), the Lenders, by written notice to the Borrower, may declare the principal of, and accrued and unpaid interest on, the Notes or any part of any of them (together with any other amounts accrued or payable under the Transaction Documents) to be, and the same shall thereupon become, immediately due and payable, without any further notice and without any presentment, demand, or protest of any kind, all of which are hereby expressly waived by the Borrower, and take any further action available at law or in equity, including, without limitation, the sale of the Loan and all other rights acquired in connection with the Loan:

(a) The Borrower shall have failed to make payment of principal and interest under the Notes when due.

(b) The Borrower shall have failed to comply with the due observance or performance of any covenant contained in any Transaction Document (other than the covenants described in (a) above), which failure shall have a Material Adverse Effect on the Borrower and such failure shall not have been cured by the Borrower within 30 days after receiving written notice of such failure from the Lenders.

(c) Any representation or warranty made by the Borrower in any Transaction Document which would have a Material Adverse Effect shall have been incorrect, false or misleading as of the date it was made.

(d) (i) The Borrower shall generally be unable to pay its debts as such debts become due, or shall admit in writing its inability to pay its debts as they come due or shall make a general assignment for the benefit of creditors; (ii) the Borrower shall declare a moratorium on the payment of its debts; (iii) the commencement by the Borrower of proceedings to be adjudicated bankrupt or insolvent, or the consent by it to the commencement of bankruptcy or insolvency proceedings against it, or the filing by it of a petition or answer or consent seeking reorganization, intervention or other similar relief under any applicable law, or the consent by it to the filing of any such petition or to the appointment of an intervenor, receiver, liquidator, assignee, trustee, sequestrator (or other similar official) of all or substantially all of its assets; (iv) the commencement against the Borrower of a proceeding in any court of competent jurisdiction under any bankruptcy or other applicable law (as now or hereafter in effect) seeking its liquidation, winding up, dissolution, reorganization, arrangement, adjustment, or the appointment of an intervenor, receiver, liquidator, assignee, trustee, sequestrator (or other similar official), and any such proceeding shall continue undismissed, or any order, judgment or decree approving or ordering any of the foregoing shall continue unstayed or otherwise in effect, for a period of ninety (90) days; (v) the making by the Borrower of an assignment for the benefit of creditors, or the admission by it in writing of its inability to pay its debt generally as they become due; or (vi) any other event shall have occurred which under any applicable law would have an effect analogous to any of those events listed above in this subsection.

(e) One or more judgments against the Borrower or any Subsidiary or attachments against any of their respective property, which could have a Material Adverse Effect remain(s) unpaid, unstayed on appeal, undischarged, unbonded or undismissed for a period of 30 days from the date of entry of such judgment.

(f) Any Authorization held by the Borrower from any Government Authority shall have been suspended, canceled or revoked and such suspension, cancellation or revocation shall not have been cured within 30 days.

(g) Any authorization necessary for the execution, delivery or performance of any Transaction Document or for the validity or enforceability of any of the Obligations under any Transaction Document is not given or is withdrawn or ceases to remain in full force or effect.

(h) The validity of any Transaction Document shall be contested by the Borrower, or any treaty, law, regulation, communiqué, decree, ordinance or policy of any jurisdiction shall purport to render any material provision of any Transaction Document invalid or unenforceable or shall purport to prevent or materially delay the performance or observance by the Borrower of the Obligations.

(i) SA has failed to comply in any material respect with the reporting requirements of the Exchange Act, if applicable.

(j) There is a failure to perform in any agreement to which the Borrower or any Subsidiary is a party with a third party or parties resulting in a right by such third party or parties to accelerate the maturity of any Indebtedness for borrowed money in an amount in excess of $50,000**.**.

(k) If an Event of Default pursuant to Section 11(a) of the Warrants (as such term is defined in the Warrants) shall have occurred.

(l) If an Event of Default under the Installment Sale Note dated March 12, 2012 from the Borrower to Eclat Holdings LLC in the principal amount of $12 million shall have occurred and such Note shall have been accelerated as a result thereof.

Section 5.5 Automatic Acceleration on Dissolution or Bankruptcy. Notwithstanding any other provisions of this Agreement, if an Event of Default under Section 5.4(d) shall occur, the principal of the Notes (together with any other amounts accrued or payable under this Agreement) shall thereupon become immediately due and payable without any presentment, demand, protest or notice of any kind, all of which are hereby expressly waived by the Borrower.

Section 5.6 Recovery of Amounts Due. If any amount payable hereunder is not paid as and when due, the Borrower hereby authorizes the Lenders to proceed, to the fullest extent permitted by applicable law, without prior notice, by right of set-off, banker's lien or counterclaim, against any moneys or other assets of the Borrower to the full extent of all amounts payable to the Lenders.

ARTICLE 6

MISCELLANEOUS

Section 6.1 Notices. Any notices required or permitted to be given under the terms hereof shall be sent by certified or registered mail (return receipt requested) or delivered personally or by courier (including a recognized overnight delivery service) or by facsimile or by electronic mail and shall be effective five (5) days after being placed in the mail, if mailed by regular United States mail, or upon receipt, if delivered personally or by courier (including a recognized overnight delivery service) or by facsimile, or when red by electronic mail (sender shall have received a "read by recipient" confirmation) in each case addressed to a party. The addresses for such communications shall be:

If to the Borrower:

Flamel US Holdings Inc.
699 Trade Center Blvd.
Chesterfield MO 63005
Phone: 636-449-1830

With copy to:

Stephen H. Willard, Esq.
2 West Newlands Street
Chevy Chase, MD 20815
Email: willardmd@aol.com

If to the Lenders:

Deerfield Management Company, L.P.
780 Third Avenue, 37th Floor
New York, NY 10017
Fax: 212-599-3075
Email: dclark@deerfield.com
Attn: David J. Clark

With a copy to:

Katten Muchin Rosenman LLP
575 Madison Avenue
New York, New York 10022
Fax: (212) 940-8776
Email: mark.fisher@kattenlaw.com
Attn: Mark I. Fisher, Esq.

Section 6.2 Waiver of Notice. Whenever any notice is required to be given to the Lenders or the Borrower under the any of the Transaction Documents, a waiver thereof in writing signed by the person or persons entitled to such notice, whether before or after the time stated therein, shall be deemed equivalent to the giving of such notice.

Section 6.3 Reimbursement of Legal and Other Expenses. If any amount owing to the Lenders under any Transaction Document shall be collected through enforcement of this Agreement, any Transaction Document or restructuring of the Loan in the nature of a work-out, settlement, negotiation, or any process of law, or shall be placed in the hands of third Persons for collection, the Borrower shall pay (in addition to all monies then due in respect of the Loan or otherwise payable under any Transaction Document) attorneys' and other fees and expenses incurred in respect of such collection.

Section 6.4 Governing Law. All questions concerning the construction, validity, enforcement and interpretation of this Agreement shall be governed by and construed and enforced in accordance with the laws of the State of New York applicable to contracts made and to be performed in such State. Each party agrees that all legal proceedings concerning the interpretations, enforcement and defense of the transactions contemplated by this Agreement (whether brought against a party hereto or its respective affiliates, directors, officers, shareholders, employees or agents) shall be commenced exclusively in the state and federal courts sitting in the City of New York. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the City of New York, borough of Manhattan for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is improper or is an inconvenient venue for such proceeding. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by law. The parties hereby waive all rights to a trial by jury.

Section 6.5 Successors and Assigns. This Agreement shall bind and inure to the respective successors and assigns of the Parties, except that Borrower may not assign or otherwise transfer all or any part of its rights under this Agreement or the Obligations without the prior written consent of the Lenders.

Section 6.6 Entire Agreement. The Transaction Documents contain the entire understanding of the Parties with respect to the matters covered thereby and supersede any and all other written and oral communications, negotiations, commitments and writings with respect thereto. The provisions of this Agreement may be waived, modified, supplemented or amended only by an instrument in writing signed by the authorized officer of each Party.

Section 6.7 Severability. If any provision of this Agreement shall be invalid, illegal or unenforceable in any respect under any law, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby. The Parties shall endeavor in good faith negotiations to replace the invalid, illegal or unenforceable provisions with valid provisions the economic effect of which comes as close as possible to that of the invalid, illegal or unenforceable provision.

Section 6.8 Counterparts. This Agreement may be executed in several counterparts, and by each Party on separate counterparts, each of which and any photocopies and facsimile copies thereof shall be deemed an original, but all of which together shall constitute one and the same agreement.

Section 6.9 Survival.

(a) This Agreement and all agreements, representations and warranties made in the Transaction Documents, and in any document, certificate or statement delivered pursuant thereto or in connection therewith shall be considered to have been relied upon by the other Parties and shall survive the execution and delivery of this Agreement and the making of the Loan hereunder regardless of any investigation made by any such other Party or on its behalf, and shall continue in force until all amounts payable under the Transaction Documents shall have been fully paid in accordance with the provisions thereof, and the Lenders shall not be deemed to have waived, by reason of making the Loan, any Event of Default that may arise by reason of such representation or warranty proving to have been false or misleading, notwithstanding that the Lenders may have had notice or knowledge of any such Event of Default or may have had notice or knowledge that such representation or warranty was false or misleading at the time the Disbursement was made.

(b) The obligations of the Borrower under Section 2.5 and the obligations of the Borrower and the Lenders under this Article 6 shall survive and remain in full force and effect regardless of the consummation of the transactions contemplated hereby, the repayment of the Loan, or the termination of this Agreement or any provision hereof.

Section 6.10 Waiver. Neither the failure of, nor any delay on the part of, any Party in exercising any right, power or privilege hereunder, or under any agreement, document or instrument mentioned herein, shall operate as a waiver thereof, nor shall any single or partial exercise of any right, power or privilege hereunder, or under any agreement, document or instrument mentioned herein, preclude other or further exercise thereof or the exercise of any other right, power or privilege; nor shall any waiver of any right, power, privilege or default hereunder, or under any agreement, document or instrument mentioned herein, constitute a waiver of any other right, power, privilege or default or constitute a waiver of any default of the same or of any other term or provision. No course of dealing and no delay in exercising, or omission to exercise, any right, power or remedy accruing to the Lenders upon any default under this Agreement, or any other agreement shall impair any such right, power or remedy or be construed to be a waiver thereof or an acquiescence therein; nor shall the action of the Lenders in respect of any such default, or any acquiescence by it therein, affect or impair any right, power or remedy of the Lenders in respect of any other default. All rights and remedies herein provided are cumulative and not exclusive of any rights or remedies otherwise provided by law.

Section 6.11 Indemnity.

(a) The Parties shall, at all times, indemnify and hold each other harmless (the "Indemnity") and each of their respective directors, partners, officers, employees, agents, counsel and advisors (each, an "Indemnified Person") in connection with any losses, claims (including the cost of defending against such claims), damages, liabilities, penalties, or other expenses arising out of, or relating to, the Transaction Documents, the extension of credit hereunder or the Loan or the use or intended use of the Loan, which an Indemnified Person may incur or to which an Indemnified Person may become subject (each, a "Loss"). The Indemnity shall not apply to the extent that a court or arbitral tribunal with jurisdiction over the subject matter of the Loss, and over the Lenders or the Borrower, as applicable, and such other Indemnified Person that had an adequate opportunity to defend its interests, determines that such Loss resulted from the gross negligence or willful misconduct of the Indemnified Person, which determination results in a final, non-appealable judgment or decision of a court or tribunal of competent jurisdiction. The Indemnity is independent of and in addition to any other agreement of any Party under any Transaction Document to pay any amount to the Lenders or the Borrower, as applicable, and any exclusion of any obligation to pay any amount under this subsection shall not affect the requirement to pay such amount under any other section hereof or under any other agreement.

(b) Promptly after receipt by an Indemnified Person under this Section 6.11 of notice of the commencement of any action (including any governmental action), such Indemnified Person shall, if a Loss in respect thereof is to be made against the Borrower under this Section 6.11, deliver to the Borrower a written notice of the commencement thereof, and the Borrower shall have the right to participate in, and, to the extent the Borrower so desires, to assume control of the defense thereof with counsel mutually satisfactory to the Borrower and the Indemnified Person, as the case may be.

(c) An Indemnified Person shall have the right to retain its own counsel with the reasonable fees and expenses to be paid by the Borrower, if, in the reasonable opinion of counsel for the Lenders, the representation by such counsel of the Indemnified Person and the Borrower would be inappropriate due to actual or potential differing interests between such Indemnified Person and any other party represented by such counsel in such proceeding. The Borrower shall pay for only one separate legal counsel for the Indemnified Persons, and such legal counsel shall be selected by the Lenders. The failure to deliver written notice to the Borrower within a reasonable time of the commencement of any such action shall not relieve the Borrower of any liability to the Indemnified Person under this Section 6.11, except to the extent that the Borrower is actually prejudiced in its ability to defend such action. The indemnification required by this Section 6.11 shall be made by periodic payments of the amount thereof during the course of the investigation or defense, as such expense, loss, damage or liability is incurred and is due and payable.

(d) Without prejudice to the survival of any other agreement of any of the Parties hereunder, the agreements and the obligations of the Parties contained in this Section 6.11 shall survive the termination of each other provision hereof and the payment of all amounts payable to the Lenders hereunder.

Section 6.12 No Usury. The Transaction Documents are hereby expressly limited so that in no contingency or event whatsoever, whether by reason of acceleration or otherwise, shall the amount paid or agreed to be paid to the Lenders for the Loan exceed the maximum amount permissible under applicable law. If from any circumstance whatsoever fulfillment of any provision hereof, at the time performance of such provision shall be due, shall involve transcending the limit of validity prescribed by law, then, ipso facto, the obligation to be fulfilled shall be reduced to the limit of such validity, and if from any such circumstance the Lenders shall ever receive anything which might be deemed interest under applicable law, that would exceed the highest lawful rate, such amount that would be deemed excessive interest shall be applied to the reduction of the principal amount owing on account of the Loan, or if such deemed excessive interest exceeds the unpaid balance of principal of the Loan, such deemed excess shall be refunded to the Borrower. All sums paid or agreed to be paid to the Lenders for the Loan shall, to the extent permitted by applicable law, be deemed to be amortized, prorated, allocated and spread throughout the full term of the Loan until payment in full so that the deemed rate of interest on account of the Loan is uniform throughout the term thereof. The terms and provisions of this Section shall control and supersede every other provision of this Agreement and the Notes.

Section 6.13 Further Assurances. From time to time, the Borrower shall perform any and all acts and execute and deliver to the Lenders such additional documents as may be necessary or as requested by the Lenders to carry out the purposes of any Transaction Document or any or to preserve and protect the Lenders' rights as contemplated therein.

Section 6.14 Action by the Lenders. Any consent, exercise of remedies or other action permitted to be taken by any Lender or the Lenders under this Agreement may be taken by the Required Lenders on behalf of such Lender or Lenders.

Section 6.15 Independent Transaction Documents. Each Transaction Document constitutes an independent agreement between the parties thereto (the "Transaction Parties") and no Transaction Document shall be construed so as to affect the rights of the Transaction Parties to their rights and remedies under another Transaction Document.

Section 6.16 **Currency**. All amounts owing under this Agreement, the Notes and the Security Agreement shall be paid in Dollars

Section 6.17 **Judgment Currency**.

(i) If, for the purpose of obtaining or enforcing judgment against the Borrower in any court in any jurisdiction with respect to any Transaction Document, it becomes necessary to convert into any other currency (such other currency being hereinafter in this Section 6.17 referred to as the "Judgment Currency") an amount due in United States dollars, the conversion shall be made at the last exchange rate published in the Wall Street Journal on the business day immediately preceding (the "Exchange Rate"):

(a) the date actual payment of the amount is due, in the case of any proceeding in the courts of New York or in the courts of any other jurisdiction that will give effect to payment being due on such date; or

(b) the date on which the French or any other non U.S. court determines, in the case of any proceeding in the courts of any other jurisdiction (the date as of which such payment is made pursuant to this Section 6.17 being hereinafter referred to as the "Judgment Payment Date").

(ii) If in the case of any proceeding in the court of any jurisdiction referred to in Section 6.17(i)(b) above, there is a change in the Exchange Rate on the date of calculation prevailing between the Judgment Payment Date and the date of actual payment of the amount due, the Borrower shall pay such adjusted amount as may be necessary to ensure that the amount paid in the Judgment Currency, when converted at the Exchange Rate prevailing on the date of payment, will produce the amount of United States dollars which could have been purchased with the amount of Judgment Currency stipulated in the judgment or judicial order at the Exchange Rate prevailing on the Judgment Payment Date.

(iii) Any amount due from the Borrower under this Section 6.15 shall be due as a separate debt and shall not be affected by judgment being obtained for any other amount due under or in respect of this Agreement and/or the Note.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the Lenders and the Borrower have caused this Agreement to be duly executed as of the 31st day of December 2012.

BORROWER:

FLAMEL US HOLDINGS INC.

By: /s/ Michael S. Anderson
Name: Michael S. Anderson
Title: CEO

LENDERS:

DEERFIELD PRIVATE DESIGN FUND II, L.P.
By: Deerfield Mgmt, L.P., its General Partner
By: J. E. Flynn Capital, LLC, its General Partner

By: /s/ James E.Flynn
Name: James E. Flynn
Title: President

DEERFIELD PRIVATE DESIGN INTERNATIONAL II, L.P.
By: Deerfield Mgmt, L.P., its General Partner
By: J. E. Flynn Capital, LLC, its General Partner

By: /s/ James E.Flynn
Name: James E. Flynn
Title: President

SCHEDULE 1

LENDER	ALLOCATION OF DISBURSEMENT AND PREPAYMENTS
Deerfield Private Design Fund II, L.P.	46.6%
Deerfield Private Design International II, L.P.	53.4%

Exhibit A

OID LEGEND

PROMISSORY NOTE

January [ ], 2013

FOR VALUE RECEIVED, Flamel US Holdings Inc., a Delaware corporation (the "Maker"), by means of this Promissory Note (this "Note"), hereby unconditionally promises to [ ] (the "Payee"), a principal amount equal to [ ], in lawful money of the United States of America and in immediately available funds, on the dates provided in the Facility Agreement.

This Note is a "Note" referred to in the Facility Agreement dated as of December 31, 2012 between the Maker, the Payee and the other parties thereto (as modified and supplemented and in effect from time to time, the "Facility Agreement"), with respect to the Loan made by the Payee thereunder. Capitalized terms used herein and not expressly defined in this Note shall have the respective meanings assigned to them in the Facility Agreement.

This Note shall bear interest on the principal amount hereof pursuant to the provisions of the Facility Agreement.

The Maker shall make all payments to the Payee of interest and principal under this Note in the manner provided in and otherwise in accordance with the Facility Agreement. The outstanding principal amount of this Note shall be due and payable in full on the Maturity Date.

If default is made in the punctual payment of principal or any other amount under this Note in accordance with the Facility Agreement, or if any other Event of Default has occurred and is continuing, this Note shall, at the Payee's option exercised at any time upon or after the occurrence and during the continuance of any such payment default or other Event of Default and in accordance with the applicable provisions of the Facility Agreement, become immediately due and payable.

All payments of any kind due to the Payee from the Maker pursuant to this Note shall be made in the full face amount thereof. Subject to the terms of the Facility Agreement, all such payments will be free and clear of, and without deduction or withholding for, any present or future taxes. The Maker shall pay all and any costs (administrative or otherwise) imposed by the Maker's banks, clearing houses, or any other financial institution, in connection with making any payments hereunder.

The Maker shall pay all costs of collection, including, without limitation, all reasonable, documented legal expenses and attorneys' fees, paid or incurred by the Payee in collecting and enforcing this Note.

Other than those notices required to be provided by Payee to Maker under the terms of the Facility Agreement, the Maker and every endorser of this Note, or the obligations represented hereby, expressly waives presentment, protest, demand, notice of dishonor or default, and notice of any kind with respect to this Note and the Facility Agreement or the performance of the obligations under this Note and/or the Facility Agreement. No renewal or extension of this Note or the Facility Agreement, no release of any Person primarily or secondarily liable on this Note or the Facility Agreement, including the Maker and any endorser, no delay in the enforcement of payment of this Note or the Facility Agreement, and no delay or omission in exercising any right or power under this Note or the Facility Agreement shall affect the liability of the Maker or any endorser of this Note.

No delay or omission by the Payee in exercising any power or right hereunder shall impair such right or power or be construed to be a waiver of any default, nor shall any single or partial exercise of any power or right hereunder preclude the full exercise thereof or the exercise of any other power or right. The provisions of this Note may be waived or amended only in a writing signed by the Maker and the Payee. This Note may be prepaid in whole or in part in accordance with the provisions of the Facility Agreement.

This Note, and any rights of the Payee arising out of or relating to this Note, may, at the option of the Payee, be enforced by the Payee in the courts of the United States of America located in the Southern District of the State of New York or in any other courts having jurisdiction. For the benefit of the Payee, the Maker hereby irrevocably agrees that any legal action, suit or other proceeding arising out of or relating to this Note may be brought in the courts of the State of New York or of the United States of America for the Southern District of New York, and hereby consents that personal service of summons or other legal process may be made as set forth in Section 5.1 of the Facility Agreement, which service the Maker agrees shall be sufficient and valid. The Maker hereby waives any and all rights to demand a trial by jury in any action, suit or other proceeding arising out of or relating to this Note or the transactions contemplated by this Note.

This Note shall be governed by, and construed in accordance with, the laws of the State of New York applicable to contracts made and to be performed in such State, without giving effect to the conflicts of laws principles thereof other than Sections 5-1401 and 5-1402 of the General Obligations Law of the State of New York.

[Signature page follows]

IN WITNESS WHEREOF, an authorized representative of the Maker has executed this Note as of the date first written above.

FLAMEL US HOLDINGS INC.

By: _____
Name:
Title:

Exhibit B

(i) amounts receivable or received under Section 9 of the Supply Agreement for Commercial Supply entered into on September 30, 2011 by and between GSK (as defined therein) and Flamel Technologies SA (the "Supply Agreement") and

(ii) amounts received or receivable under Article 3 of the License Agreement dated March 26, 2003 by and between GSK (as defined therein) and Flamel Technologies SA (the "License Agreement")

CONFIDENTIAL TREATMENT REQUESTED

[***] – CONFIDENTIAL PORTIONS OF THIS AGREEMENT WHICH HAVE BEEN REDACTED ARE MARKED WITH BRACKETS ("[***]"). THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE UNITED STATES SECURITIES AND EXCHANGE COMMISSION.

ROYALTY AGREEMENT

THIS ROYALTY AGREEMENT (this "***Agreement***") is dated as of December 31, 2012, by and among **ÉCLAT PHARMACEUTICALS, LLC (the** "***Payor***"), and **DEERFIELD PRIVATE DESIGN FUND II, L.P.** and **HORIZON SANTÉ FLML, SARL** (the "***Buyers***").

Whereas, the Payor desires to sell, and the Buyers desire to purchase, a royalty on the net sales of certain products now or hereafter sold by the Payor for the consideration and on the terms set forth herein, the Parties to this Agreement, intending to be legally bound, agree as follows:

1. Definitions. Certain capitalized terms used in this Agreement are defined in Exhibit A.

2. Royalty.

(a) Royalty Amount**.** The Payor shall pay 1.75% of Net Sales of Products (the "***Royalty***") to the Buyers.

(b) Payment of the Royalty. The Royalty shall accrue daily and shall be paid quarterly in arrears for each calendar quarter from and after the date hereof until the expiration of the quarter ending December 31, 2024 (the "***Royalty Term***"). No later than two Business Days following the date Flamel Technologies SA ("***Flamel***") files its Earnings Report for each calendar quarter or if Flamel is not obligated to file reports under the Securities Exchange Act of l934, following its preparation of its internal financial statements (but in no event later than sixty days following the last day of each of the first three quarters and one hundred twenty days following the last day of the fourth quarter of each calendar year), the Payor shall pay or cause to be paid to Buyers the Royalty for such quarter (each, a "***Royalty Payment***"), together with a statement showing all Net Sales of Products and the computation of the Royalty for such quarter (each a "***Royalty Calculation***"). All Royalty Payments shall be made by wire transfer of immediately available funds to the account(s) designated in writing by the Buyers no later than five Business Days prior to the date such Royalty Payment shall be due.

(c) Delinquent Royalty Payments. Any Royalty Payment not paid when due shall bear interest at the Default Rate, compounded daily, or the highest rate then permitted by applicable law, whichever is less.

(d) Audit Right. Upon not less than ten Business Days notice (the "***Audit Notice***"), the Buyers may audit the books and records of the Payor once every calendar year to determine the computation of any Royalty Payment for up to three years prior to the date of the Audit Notice, provided that no audit for a given year shall be repeated pursuant to this provision, but shall be final in all respects for the period reviewed upon completion of the audit. Such audit shall be conducted during normal business hours at the Buyers' cost, provided that any Representative involved enters into a reasonable confidentiality agreement with the Payor (to be approved by the Payor in its sole reasonable discretion) prior to commencing any such audit. The Payor shall provide the Buyers and their Representatives with reasonable access to all such books and records and shall reasonably cooperate with the Buyers' and their Representatives' efforts to conduct such audits. The Buyers may object to any Royalty Calculation by delivering a notice of objection (a "***Royalty Objection Notice***"), which shall specify the disputed items in the Royalty Calculation and shall describe in reasonable detail the basis for such objection, as well as the amount in dispute. If the Buyers deliver Payor such Notice, Payor and Buyers shall negotiate in good faith for up to ten Business Days to resolve the disputed items and agree upon the resulting amount of the disputed Royalty Payment. If Payor and Buyers are unable to reach such agreement, all unresolved disputed items shall be promptly referred to the Reviewing Accountant. The Reviewing Accountant shall render a written report on only such items as promptly as practicable, but in no event greater than 30 days after such referral. If disputed items are submitted to the Reviewing Accountant, Payor and Buyers shall furnish to the Reviewing Accountant such work papers, schedules and other documents and information relating to the items as the Reviewing Accountant may reasonably request. The Reviewing Accountant shall resolve the disputed items based solely on the provisions of this Agreement and the presentations by Payor and Buyers, and not by independent review. The Reviewing Accountant will not have the power to amend this Agreement. The resolution of the dispute and the calculation of the Royalty Payment by the Reviewing Accountant shall be final and binding on the Payor and the Buyers. If there has been an underpayment of the Royalty Payment due for the period being audited of more than five percent (5%) of the amount due for the period, the Payor shall reimburse the Buyers for the reasonable out-of-pocket costs (including the Reviewing Accountants' fees) incurred by the Buyers pursuant to this **Section 2(d)**.

(e) Sale of Products; Assignment or Sublicenses. The Payor shall pay the Royalty Payments on all Product sales by Flamel and its Affiliates and all direct or indirect licensees and assignees or successive licensee and assignees of any rights to sell, market or otherwise distribute Products, and the provisions of this **Section 2** shall apply to all such sales as if made directly by the Payor.

3. Purchase Price. In consideration of the sale and payment of the Royalty, each Buyer shall pay to the Payor the amount set forth next to such Buyer's name on **Exhibit B** hereto in such manner as the Payor shall direct.

4. Covenants of the Payor

(a) Regulatory Approvals. The Payor shall use all commercially reasonable efforts to obtain approval of each NDA necessary to sell each Product in the United States of America. Without limiting the foregoing, the Payor shall (A) initiate development and manufacturing of all Products through a third-party (if this has not already occurred as of date of this Agreement) and (B) pursue a pre-IND/pre-NDA meeting with the FDA for each Product (if this has not already occurred as of the date of this Agreement). The Payor shall also use commercially reasonable efforts to (x) cause registration batches of each Product to be manufactured and (y) cause stability testing to be completed for each Product, in each case unless the FDA states in such meeting that such Product would not be approved without clinical trials or other unexpected conditions to approval that would make continued efforts to obtain the NDA necessary to commercialize the Product not commercially viable.

(b) Marketing of Products. Upon approval to market any Product, the Payor shall take all commercially reasonable and appropriate actions to manufacture or have manufactured, package, label, distribute, offer for sale and sell such Product.

(c) Credit Facility Restrictions. The Payor represents and warrants that there are no restrictions or limitations on its ability to make the payments that are or may be required to be paid to the Buyers under this Agreement in any Contract. The Payor shall not enter into, or amend, any Contract of it or its Affiliates after the date hereof the effect of which is to place any restrictions or limitations on the Payor's ability to make the payments that are required to be paid to the Buyers under this Agreement.

(d) No Transfer Without Consent. The Payor shall not transfer (whether by sale, assignment, merger, change of control, conveyance of rights, deed of trust, lien, license, sublicense, seizure or other transfer of any sort, voluntary or involuntary, including by operation of law) any of its right, title or interest in or to the Product Intellectual Property or Product Regulatory Rights unless the assignee/transferee agrees in writing to assume (in addition to the Payor) all of the Payor's obligations under this Agreement; provided, however, that such requirement shall not apply to (i) the direct or indirect license of Product Intellectual Property or Product Regulatory Rights to make, have made, use, promote, import, offer to sell or sell Products solely on behalf of, or for the benefit of, the Payor or (ii) the direct or indirect license of Product Intellectual Property or Product Regulatory Rights for any other reason.

(e) Acceleration. Notwithstanding anything to the contrary contained in this Agreement, upon and at any time after the occurrence of any Acceleration Trigger Event, (x) an amount equal to the Accelerated Value shall automatically become immediately due and payable without presentment, demand, protest, notice of intent to accelerate or other notice or legal process of any kind, all of which are hereby knowingly and expressly waived by the Payor, and (y) the Buyers may exercise any and all other rights and remedies available to them under this Agreement and applicable law. At least once per year, the Payor will update in good faith its sales projections for the Products for such period as the Buyers shall reasonably request..

5. Representations and Warranties of the Payor. The Payor represents and warrants to the Buyers as follows as of the date of this Agreement:

(a) Organization; Good Standing. The Payor is duly organized, validly existing and in good standing under the laws of the jurisdiction of its formation. The Payor has the requisite power and authority to own, lease or use its properties and assets and to conduct its business as presently conducted.

(b) Consents and Approvals; No Violation. Neither the execution and delivery of this Agreement by the Payor nor the performance of its obligations hereunder nor the consummation by the Payor of the transactions contemplated hereby will: (i) conflict with or result in a breach, violation, or default of or under the organizational document of the Payor, (ii) require the consent of, or notice to, any Person under, conflict with, result in a violation or breach of, constitute a default or an event that, with or without notice or lapse of time or both, would constitute a default under, result in the acceleration of or create in any party the right to accelerate, terminate, modify or cancel any Contract to which the Payor is a party or by which the Payor is bound or to which any of its properties and assets are subject or any Governmental Authorization affecting the properties, assets or business of the Payor, (iii) result in the creation of any Encumbrance (other than Permitted Encumbrances) on the assets of the Payor, or (iv) conflict with or result in a violation or breach of any provision of any Legal Requirement applicable to the Payor.

(c) Absence of Changes. Since March 13, 2012:

(i) There has been no transfer, assignment, sale, distribution, or Encumbrance of any Product or of any Product Intellectual Property or Product Regulatory Rights, and there has been no agreement to do so;

(ii) The Payor has not adopted any plan of consolidation, reorganization, liquidation or dissolution or filed a petition in bankruptcy under any provisions of federal or state bankruptcy law or consented to the filing of any bankruptcy petition against it under any similar law;

(iii) The Payor has not formed any Affiliates, or made any capital investment in or acquired any equity interest in any other Entity;

(iv) To the knowledge of the Payor, no Person other than the Payor has submitted a product containing the same active pharmaceutical ingredient for approval by the FDA other than with respect to **[***]** for a product that is described on an exhibit to this Agreement;

(v) As of the date hereof, the FDA has not expressed any disapproval, formally or informally, orally or in writing, of the development program proposed by the Payor for any of the Products.

(vi) As of the date hereof, the FDA has not formally or informally, orally or in writing, advised the Payor that it does not intend to approve any Product in the manner proposed by the Payor or based upon the information provided or to be provided by the Payor.

(d) Compliance with Laws.

The Payor is in compliance with all Legal Requirements applicable to it or its business, properties or assets. The Payor has not received any written notice from any Governmental Body or any other Person regarding (i) any actual, alleged or potential material violation of or material liability under any Legal Requirement, or (ii) any actual, alleged, or potential material obligation of the Payor to undertake or pay for any response action required by any Legal Requirement.

(e) Regulatory Compliance.

(i) The Payor has not received any notices or correspondence from the FDA or any other Governmental Body exercising comparable authority requiring the recall, termination or suspension of sale of any Product or otherwise alleging that the Payor is not in compliance in all material respects with all applicable Legal Requirements.

(ii) Neither the Payor, nor any officer or employee of the Payor, nor, to the Payor's knowledge, any agents or contractor of the Payor is the subject of any pending or threatened investigation by the FDA pursuant to its "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities" Final Policy set forth in 56 Fed. Reg. 46191 (September 10, 1991) and any amendments thereto, or by any other comparable Governmental Body to invoke any similar policy. None of the Payor nor any officer or employee of the Payor, nor, to the Payor's knowledge, any agent or contractor of the Payor has (A) made any untrue statement of material fact or fraudulent statement to the FDA, DEA, or any other Governmental Body; (B) failed to disclose a material fact required to be disclosed to the FDA, DEA, or any other Governmental Body, or (C) committed an act, made a statement, or failed to make a statement that would reasonably be expected to provide the basis for the FDA or any other Governmental Body to invoke the FDA's "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities" Final Policy.

(iii) Neither the Payor nor any officer or employee of the Payor has been debarred or been convicted of any crime or engaged in any conduct that did or could result in debarment under 21 U.S.C. § 335a, exclusion from federal healthcare programs under 42 U.S.C. § 1320a-7, disqualification as a clinical investigator under 21 C.F.R. § 312.70 or any similar Legal Requirements, and none of the Payor or any officer or employee of the Payor has engaged in any conduct that would reasonably be expected to result in debarment, exclusion, or disqualification from U.S. federal health care programs.

(iv) Neither the Payor, nor any officer of the Payor has received any written notice or communication from the FDA, DEA, or other Governmental Body requiring termination or suspension of sale of any of Product or alleging noncompliance with any applicable FDA Law, DEA Law, or other applicable Legal Requirements with regard to any Product. Neither the Payor nor any officer of the Payor has been or is subject to any enforcement proceedings by the FDA, DEA, or other Governmental Body and, to the Payor's knowledge, no such proceedings have been threatened.

6. [Reserved]

7. Miscellaneous Provisions.

(a) Further Assurances. Each of the parties hereto shall, and shall cause their respective Affiliates to, execute and deliver such additional documents, instruments, conveyances and assurances and take such further actions as may be reasonably required to give effect to the transactions contemplated by this Agreement.

(b) Survival of Representations and Warranties. The representations and warranties of the parties contained in this Agreement shall survive and remain in full force and effect through the expiration of the Royalty Term.

(c) Amendment. This Agreement may not be amended except by an instrument in writing signed by the Payor and the Buyers.

(d) Waiver. No failure on the part of any Party to exercise any power, right, privilege or remedy under this Agreement, and no delay on the part of any Party in exercising any power, right, privilege or remedy under this Agreement, shall operate as a waiver of such power, right, privilege or remedy; and no single or partial exercise of any such power, right, privilege or remedy shall preclude any other or further exercise thereof or of any other power, right, privilege or remedy.

No Party shall be deemed to have waived any claim arising out of this Agreement, or any power, right, privilege or remedy under this Agreement, unless the waiver of such claim, power, right, privilege or remedy is expressly set forth in a written instrument duly executed and delivered on behalf of such Party; and any such waiver shall not be applicable or have any effect except in the specific instance in which it is given.

(e) Entire Agreement; Counterparts; Exchanges by Facsimile. This Agreement, and the other agreements referred to in this Agreement constitute the entire agreement and supersede all prior agreements and understandings, both written and oral, among or between any of the Parties with respect to the subject matter hereof and thereof; provided, however, that any existing confidentiality agreements shall not be superseded and shall remain in full force and effect in accordance with its terms. This Agreement may be executed in several counterparts, each of which shall be deemed an original and all of which shall constitute one and the same instrument. The exchange of a fully executed Agreement (in counterparts or otherwise) by all Parties by facsimile or portable document format (PDF) shall be sufficient to bind the Parties to the terms and conditions of this Agreement.

(f) Applicable Law; Jurisdiction. THIS AGREEMENT SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH, THE LAWS OF THE STATE OF NEW YORK, REGARDLESS OF THE LAWS THAT MIGHT OTHERWISE GOVERN UNDER APPLICABLE PRINCIPLES OF CONFLICTS OF LAWS. EACH OF THE PARTIES TO THIS AGREEMENT (A) CONSENTS TO SUBMIT ITSELF TO THE PERSONAL JURISDICTION OF THE FEDERAL AND STATE COURTS OF THE STATE OF NEW YORK IN ANY ACTION OR PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT OR ANY OF THE TRANSACTIONS CONTEMPLATED HEREUNDER, (B) AGREES THAT ALL CLAIMS IN RESPECT OF SUCH ACTION OR PROCEEDING MAY BE HEARD AND DETERMINED IN SUCH COURT, (C) AGREES THAT IT SHALL NOT ATTEMPT TO DENY OR DEFEAT SUCH PERSONAL JURISDICTION BY MOTION OR OTHER REQUEST FOR LEAVE FROM ANY SUCH COURTS, AND (D) AGREES NOT TO BRING ANY ACTION OR PROCEEDING (INCLUDING COUNTER-CLAIMS) ARISING OUT OF OR RELATING TO THIS AGREEMENT OR ANY OF THE TRANSACTIONS CONTEMPLATED HEREUNDER IN ANY OTHER COURT. EACH OF THE PARTIES WAIVES ANY DEFENSE OF INCONVENIENT FORUM TO THE MAINTENANCE OF ANY ACTION OR PROCEEDING SO BROUGHT AND WAIVES ANY BOND, SURETY OR OTHER SECURITY THAT MIGHT BE REQUIRED OF ANY OTHER PARTY WITH RESPECT THERETO. ANY PARTY MAY MAKE SERVICE ON ANOTHER PARTY BY SENDING OR DELIVERING A COPY OF THE PROCESS TO THE PARTY TO BE SERVED AT THE ADDRESS AND IN THE MANNER PROVIDED FOR THE GIVING OF NOTICES HEREIN. NOTHING IN THIS **SECTION 7(f)**, HOWEVER, SHALL AFFECT THE RIGHT OF ANY PARTY TO SERVE LEGAL PROCESS IN ANY OTHER MANNER PERMITTED BY LAW.

(g) Assignability; No Third Party Beneficiaries. This Agreement shall be binding upon, and shall be enforceable by and inure solely to the benefit of, the Parties and their respective successors and assigns. No Party may assign any of its rights or obligations hereunder without the prior written consent of the other Party, and any attempted assignment or delegation of this Agreement or any of such rights or obligations by such Party without the other Party's prior written consent shall be void and of no effect; provided that a Buyer may assign its rights to payments under this Agreement to any other Person without the prior written consent of the Payor or any other Person. Nothing in this Agreement, express or implied, is intended to or shall confer upon any Person any right, benefit or remedy of any nature whatsoever under or by reason of this Agreement.

(h) Notices. Any notice or other communication required or permitted to be delivered to a Party under this Agreement shall be in writing and shall be deemed properly delivered, given and received when delivered by hand, by registered mail, by courier or express delivery service or by facsimile to such address or facsimile telephone number as each Party shall have specified in a written notice given to the other Party.

(i) Severability. Any provision of this Agreement that is invalid or unenforceable in any situation in any jurisdiction shall not affect the validity or enforceability of the remaining provisions of this Agreement or the validity or enforceability of the offending provision in any other situation or in any other jurisdiction. If a final judgment of a court of competent jurisdiction declares that any provision of this Agreement is invalid or unenforceable, the Parties agree that the court making such determination shall have the power to limit such provision, to delete specific words or phrases or to replace such provision with a provision that is valid and enforceable and that comes closest to expressing the intention of the invalid or unenforceable provision, and this Agreement shall be valid and enforceable as so modified. If such court does not exercise the power granted to it in the prior sentence, the Parties agree to replace such invalid or unenforceable provision with a valid and enforceable provision that will achieve, to the extent possible, the economic, business and other purposes of such invalid or unenforceable provision.

(j) Other Remedies; Specific Performance. Any and all remedies herein expressly conferred upon a Party will be deemed cumulative with and not exclusive of any other remedy conferred hereby, or by law or equity upon such Party, and the exercise by a Party of any one remedy will not preclude the exercise of any other remedy. The Parties agree that irreparable damage would occur in the event that any provision of this Agreement were not performed in accordance with its specific terms or were otherwise breached. It is accordingly agreed that the Parties shall be entitled to seek an injunction or injunctions to prevent breaches of this Agreement and to enforce specifically the provisions hereof, this being in addition to any other remedy to which they are entitled at law or in equity.

(k) Judgment Currency. If, for the purpose of obtaining or enforcing judgment against any Party in any court in any jurisdiction with respect to this Agreement it becomes necessary to convert into any other currency (such other currency being hereinafter referred to as the "Judgment Currency") to an amount due in United States dollars, the conversion shall be made at the last exchange rate published in the Wall Street Journal on the Business Day immediately preceding (the "Exchange Rate"):

the date actual payment of the amount is due, in the case of any proceeding in the courts of Delaware or in the courts of any other jurisdiction that will give effect to payment being due on such date; or

the date on which the French or any other non U.S. court determines, in the case of any proceeding in the courts of any other jurisdiction (the date as of which such payment is made being hereinafter referred to as the "Judgment Payment Date").

If in the case of any proceeding in the court of any jurisdiction referred to above, there is a change in the Exchange Rate on the date of calculation prevailing between the Judgment Payment Date and the date of actual payment of the amount due, the applicable Party shall pay such adjusted amount as may be necessary to ensure that the amount paid in the Judgment Currency, when converted at the Exchange Rate prevailing on the date of payment, will produce the amount of United States dollars which could have been purchased with the amount of Judgment Currency stipulated in the judgment or judicial order at the Exchange Rate prevailing on the Judgment Payment Date.

Any amount due from the Payor under this **Section 7(k)** shall be due as a separate debt and shall not be affected by judgment being obtained for any other amount due under or in respect of this Agreement.

(l) Construction. For purposes of this Agreement, whenever the context requires: the singular number shall include the plural, and vice versa; and any gender shall include all genders.

The Parties agree that any rule of construction to the effect that ambiguities are to be resolved against the drafting Party shall not be applied in the construction or interpretation of this Agreement.

As used in this Agreement, the words “include” and “including,” and variations thereof, shall not be deemed to be terms of limitation, but rather shall be deemed to be followed by the words “without limitation.”

Except as otherwise indicated, all references in this Agreement to “Sections,” “Exhibits” and “Schedules” are intended to refer to Sections of this Agreement and Exhibits and Schedules to this Agreement.

The headings contained in this Agreement are for convenience of reference only, shall not be deemed to be a part of this Agreement and shall not be referred to in connection with the construction or interpretation of this Agreement.

[Remainder of page intentionally left blank; signature pages follow.]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed as of the date first above written.

ÉCLAT PHARMACEUTICALS, LLC

By: /s/ Michael S. Anderson
Name: Michael S. Anderson
Title: CEO

DEERFIELD PRIVATE DESIGN FUND II, L.P.
By: Deerfield Mgmt L.P., its General Partner

By: J.E. Flynn Capital, LLC, its General Partner

By: /s/ James E. Flynn
Name: James E. Flynn
Title: President

HORIZON SANTÉ FLML, SÀRL

By: /s/ Alexis Cazé
Name: Alexis Cazé
Title: Manager A

By: /s/ Florence Gerardy
Name: Florence Gerardy
Title: Manager B

EXHIBIT A

CAPITALIZED TERMS

"**Accelerated Value**" shall mean as of any date of determination, the amount of future Royalty Payments would be paid to Buyers using the Payor's good faith projections of future sales of the Products at the time of the Acceleration Trigger Event, discounted to present value as of the date of the Acceleration Trigger Event using quarterly compounding and a discount rate of 4%.

"**Acceleration Trigger Event**" shall mean the occurrence of any one or more of the following events:

(a) The Payor shall (i) file a voluntary petition or commence a voluntary case seeking liquidation, winding-up, reorganization, dissolution, arrangement, readjustment of debts or any other relief under any applicable bankruptcy, insolvency or similar law now or hereafter in effect, (ii) apply for or consent to the appointment of or taking possession by a custodian, trustee, receiver or similar official for or of itself or all or a substantial part of its properties or assets, (iii) fail generally, or admit in writing its inability, to pay its debts generally as they become due, (iv) make a general assignment for the benefit of creditors or (v) take any action to authorize or approve any of the foregoing; or

(b) Any involuntary petition or case shall be filed or commenced against the Payor seeking liquidation, winding-up, reorganization, dissolution, arrangement, readjustment of debts, the appointment of a custodian, trustee, receiver or similar official for it or all or a substantial part of its properties or any other relief under any other applicable bankruptcy, insolvency or similar law now or hereafter in effect, and such petition or case shall continue undismissed and unstayed for a period of 60 days; or an order, judgment or decree approving or ordering any of the foregoing shall be entered in any such proceeding.

"***Affiliate***". An Entity shall be deemed to be a "***Affiliate***" of another Person if such Person directly or indirectly owns or purports to own, beneficially or of record, (a) an amount of voting securities of other interests in such Entity that is sufficient to enable such Person to elect at least a majority of the members of such Entity's board of directors or other governing body, or (b) at least 50% of the outstanding equity, voting, beneficial or financial interests in such Entity.

"***ANDA***" means Abbreviated New Drug Application.

"***Business Day***" shall mean any day other than a day on which banks in New York, NY or Paris, France are authorized or obligated to be closed.

"***Contract***" shall, with respect to any Person, mean any written, oral or other agreement, contract, subcontract, lease (whether real or personal property), mortgage, understanding, arrangement, instrument, note, option, warranty, purchase order, license, sublicense, insurance policy, benefit plan or legally binding commitment or undertaking of any nature to which such Person is a party or by which such Person or any of its assets are bound or affected under applicable law.

"***Copyright***" means all copyrights and moral rights, including the legal right provided by the Copyright Act of 1976, as amended, to the expression contained in any work of authorship fixed in any tangible medium of expression together with any similar rights arising in any other country as a result of statute or treaty, and all registrations, applications, renewals, extensions and reversions thereof.

"***DEA***" means the United States Drug Enforcement Administration or any successor agency thereto.

"***Default Rate***" shall mean 15% per annum or such lesser rate as shall be allowable by law.

"***Earnings Report***" means during any period when Flamel is obligated to file reports under the provisions of the Securities Exchange Act of 1934, the Form 6-K filed by Flamel containing its financial information for such quarter.

"***Encumbrance***" shall mean any lien, pledge, hypothecation, charge, mortgage, security interest, encumbrance, easement, condition, preemptive right, community property interest, right of first refusal or right of first offer, or similar restriction of any kind, including any restriction on the voting of any security or equity interest, any restriction on the transfer of any security, equity interest or other asset, and any restriction on the receipt of any income or exercise of any other attribute of ownership, under any Legal Requirement.

"***Entity***" shall mean any corporation (including any non-profit corporation), partnership (including any general partnership, limited partnership or limited liability partnership), joint venture, estate, trust, company (including any company limited by shares, limited liability company or joint stock company), firm, society or other enterprise, association, organization or entity.

"***FDA***" means the United States Food and Drug Administration or any successor agency thereto.

"***Governmental Authorization***" shall mean any: (a) permit, license, certificate, franchise, permission, variance, exceptions, orders, clearance, registration, qualification or authorization issued, granted, given or otherwise made available by or under the authority of any Governmental Body or pursuant to any Legal Requirement; or (b) right under any Contract with any Governmental Body.

"***Governmental Body***" shall mean any: (a) nation, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature; (b) federal, state, local, municipal, foreign or other government; (c) governmental or quasi-governmental authority of any nature (including any governmental division, department, agency, commission, instrumentality, official, ministry, fund, foundation, center, organization, unit, body or other Entity and any court or other tribunal, and for the avoidance of doubt, any Taxing authority); or (d) self-regulatory organization (including the NASDAQ Global Market).

"***Know-How***" means ideas, designs, concepts, compilations of information methods, techniques, methodologies, procedures and processes, compositions, specifications, techniques, technical data and information, designs, drawings, customer lists, supplier lists, pricing and financial information, plans and proposals, algorithms and formulas, whether or not patentable.

"***Legal Requirement***" shall mean any federal, state, foreign, local or municipal or other law, statute, constitution, principle of common law, resolution, ordinance, code, edict, decree, rule, regulation, judgment, ruling or requirement issued, enacted, adopted, promulgated, implemented or otherwise put into effect by or under the authority of any Governmental Body.

"***Mark***" means any word, name, symbol, logos or device used by a Person to identify its goods or services, whether or not registered, all goodwill associated therewith, and any right that may exist to obtain a registration with respect thereto from any Governmental Body and any rights arising under any such application, together with all registrations, renewals, extensions and reversions thereof. As used in this Agreement, the term "Mark" includes all of the foregoing, including trademarks and service marks.

"***Net Sales***" shall mean, without duplication, the gross amount invoiced for Products sold globally in *bona fide*, arm's length transactions, less customary deductions determined without duplication in accordance with the selling Person's customary accounting methods as generally and consistently applied for: (i) cash or terms discounts, (ii) sales, use and value added taxes (if and only to the extent included in the gross invoice amount), (iii) reasonable and customary accruals for third party rebates and chargebacks, (iv) returns and (v) recalls.

"***Party***" or "***Parties***" shall mean the Buyers and the Payor.

"***Patent***" means any patent granted by the United States Patent and Trademark Office or by the comparable agency of any other country, and any renewal, thereof, and any rights arising under any patent application filed with the United States Patent and Trademark Office or the comparable agency of any other country and any rights that may exist to file any such application, including all continuations, divisional, continuations-in-part and provisionals and patents issuing thereon, and all reissues, reexaminations, substitutions, renewals and extensions thereof.

"***Permitted Encumbrances***" means (a) statutory liens for Taxes that are not yet due and payable or Taxes that are being contested in good faith by appropriate proceedings; (b) statutory, common law or civil law liens to secure obligations to landlords, lessors or renters under leases or rental agreements confined to the premises rented pursuant to and which are not, individually or in the aggregate, material to the business of the Payor; (c) deposits or pledges made in connection with, or to secure payment of, workers' compensation, unemployment insurance, old age pension or other social security programs mandated under Legal Requirements, which are not, individually or in the aggregate, material to the business of the Payor; (d) statutory, common or civil law liens in favor of carriers, warehousemen, mechanics and materialmen to secure claims for labor, materials or supplies and other like liens with respect to amounts not yet due and payable, which are not, individually or in the aggregate, material to the business of the Payor.

"***Person***" shall mean any individual, Entity or Governmental Body.

"***Product Intellectual Property***" shall mean all Proprietary Rights held or licensed by the Payor and Flamel and their Affiliates that is, or may hereafter be, necessary to develop, make, have made, promote, market or sell the Products in the United States.

"***Product Regulatory Rights***" shall mean each and every investigational new drug application or new drug application and/or state license or registration that is held or obtained (if any) that is necessary to develop, conduct clinical trials relating to, manufacture, have manufactured, distribute, promote, market or sell the Products in the United States.

"***Products***" shall mean (i) the drugs [***], [***], [***] and [***], and (ii) [***].

"***Proprietary Rights***" means, with respect to a Person, all Copyrights, Marks, Trade Names, Trade Secrets, Patents, intellectual property rights in inventions and discoveries, intellectual property rights in internet web sites and internet domain names and subdomain names and intellectual property rights in Know-How, owned or used by such Person.

"***Representatives***" shall mean directors, officers, other employees, agents, attorneys, accountants, advisors and representatives.

"***Reviewing Accountant***" means Grant Thornton or such other accounting firm designated by the Buyers.

"***Tax***" shall mean any federal, state, local, foreign or other taxes, levies, charges and fees or other similar assessments or liabilities in the nature of a tax, including, without limitation, any income tax, franchise tax, capital gains tax, gross receipts tax, value-added tax, surtax, estimated tax, unemployment tax, national health insurance tax, excise tax, ad valorem tax, transfer tax, stamp tax, sales tax, use tax, property tax, business tax, withholding tax, payroll tax, customs duty, alternative or add-on minimum or other tax of any kind whatsoever, and including any fine, penalty, assessment, addition to tax or interest, whether disputed or not.

"***Trade Names***" means any words, name or symbol used by a Person to identify its business.

"***Trade Secrets***" means business or technical information of any Person including, but not limited to, customer lists, marketing data and Know-How, that is not generally known to other Persons who are not subject to an obligation of nondisclosure and that derives actual or potential commercial value from not being generally known to other Persons.

EXHIBIT B

ALLOCATION OF PURCHASE PRICE

Buyers		Purchase Price
Deerfield Private Design Fund II, L.P.	$	1,211,600
Horizon Santé FLML Sarl	$	1,388,400
Total:	$	2,600,000

Exhibit 4.9

CONFIDENTIAL TREATMENT REQUESTED

[***] – CONFIDENTIAL PORTIONS OF THIS AGREEMENT WHICH HAVE BEEN REDACTED ARE MARKED WITH BRACKETS ("[***]"). THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE UNITED STATES SECURITIES AND EXCHANGE COMMISSION.

SECURITY AGREEMENT

This Security Agreement (this "**Agreement**"), dated as of February 4, 2013, is entered into between **Eclat Pharmaceuticals LLC ("Eclat")** in favor of the parties and in the capacities identified on the signature page of this Agreement as a secured party (together, the "**Secured Party**").

WITNESSETH:

WHEREAS, Eclat has entered into a Royalty Agreement, dated as of December 31, 2012, with the Buyers named therein (the "**Royalty Agreement**"),

WHEREAS, Flamel Holdings Inc., the holder of the equity interests in Eclat, has entered into a Facility Agreement dated as of December 31, 2012 with the Lenders named therein (the "**Facility Agreement**"), and

WHEREAS, certain capitalized terms used in this Agreement are defined in Section 9,

NOW, THEREFORE, in consideration of the mutual agreements set forth herein, Eclat and the Secured Party agree as follows:

1. Grant of Security Interest.

(a) To secure payment and performance of the Obligations, Eclat hereby grants to Secured Party a security interest (the "**Security Interest**") in the Product Intellectual Property and Product Regulatory Rights and all proceeds and products thereof (the "**Collateral**").

Notwithstanding anything to the contrary contained herein, the Security Interest shall not extend to, and the Collateral shall not include (collectively, the "**Excluded Collateral**"): (1) any contract of Eclat if the grant of the Security Interest in such contract, under the terms of or under applicable laws, would result in the termination thereof or give the other parties thereto the right to terminate, accelerate or otherwise alter Eclat's rights, titles and interests thereunder (including upon the giving of notice or the lapse of time or both); provided, however, that (i) any limitation described above shall only apply to the extent that such limitation could not be rendered ineffective pursuant to the UCC or any other applicable laws and (ii) if such limitations is eliminated to the extent sufficient to permit any such item to become Collateral hereunder, the Security Interest in such contract shall be automatically and simultaneously granted hereunder and such contract shall be included as Collateral hereunder.

(b) Eclat shall not to enter into any agreement that prohibits the creation of the Security Interest other than (i) customary restrictions and conditions contained in agreements relating to the sale of property pending such sale, (ii) customary provisions in contracts restricting the assignment thereof, and (iii) restrictions on the pledge of interests in any joint venture contained in the applicable joint venture agreement.

(c) Perfection of Security Interests.

(i) Eclat authorizes Secured Party to file such financing statements naming Secured Party or its designee as the secured party and Eclat as debtor, as Secured Party may require in order to perfect the Security Interest required by Article 9 of the UCC, together with any amendment and continuations with respect thereto; provided, however, that if requested by Eclat, any such financing statement or amendment or continuation shall specifically identify any Excluded Collateral. Eclat shall not file, or permit or cause to be filed, any correction or termination statement with respect to any financing statement (or amendment or continuation thereof).

(ii) Eclat shall take any other action reasonably requested by Secured Party to cause the attachment and perfection of, and the ability of Secured Party to enforce, the Security Interest.

2. Notice of Change in Certain Information. Eclat shall not change (a) its name as it appears in official filings in the state of its organization, (b) its chief executive office or sole place of business, (c) the type of entity that it is, (d) its organization identification number, if any, issued by its state of organization, or (e) its state of organization, in each case, unless all filings have been made under the UCC that are required in order for the Secured Party to continue following such change to have a valid and perfected security interest in the Collateral.

3. Remedies.

Upon the occurrence and during the continuance of an Event of Default, (i) Secured Party shall have the right to exercise any right and remedy provided for herein, under the UCC and at law or equity generally, including, without limitation, the right to foreclose the Security Interest and to realize upon any Collateral by any available judicial procedure and/or to take possession of the Collateral with or without judicial process; and (ii) with or without having the Collateral at the time or place of sale, Secured Party may sell the Collateral, or any part thereof, at public or private sale, at any time or place, in one or more sales, at such price or prices, and upon such terms, either for cash, credit or future delivery, as Secured Party may elect.

4. Representations and Warranties. Eclat hereby represents and warrants to Secured Party as of the date hereof that:

(a) Eclat is a limited liability company duly organized and validly existing under the laws of Delaware.

(b) The exact legal name of Eclat is set forth on the signature page of this Agreement.

(c) The chief executive office and mailing address of Eclat are located only at the address set forth on Schedule 4(c).

5. Expenses; Secured Party's Right to Perform on Eclat's Behalf.

(a) Eclat's agreements hereunder shall be performed by it at its sole expense.

(b) If Eclat shall fail to do any act which it has agreed to do hereunder, Secured Party may (but shall not be obligated to) do or cause the act to be done, either in its name or on behalf of Eclat, and Eclat hereby irrevocably authorizes Secured Party so to act.

6. No Waivers of Rights hereunder; Rights Cumulative.

(a) No delay by Secured Party in exercising any right hereunder, or in enforcing any of the Obligations, shall operate as a waiver thereof, nor shall any single or partial exercise of any right preclude other or further exercises thereof or the exercise of any other right. No waiver of any of the Obligations shall be enforceable against Secured Party unless in writing and signed by Secured Party, and unless it expressly refers to the provision affected, any such waiver shall be limited solely to the specific event waived.

(b) All rights granted Secured Party hereunder shall be cumulative and shall be supplementary of and in addition to those granted or available to Secured Party under any other agreement with respect to the Obligations or under applicable law and nothing herein shall be construed as limiting any such other right.

7. Termination. This Agreement shall continue in full force and effect until all Obligations shall have been paid in full.

8. Applicable Law and Consent to Non-Exclusive New York Jurisdiction.

(a) This Agreement shall be construed in accordance with the laws of the State of New York, without giving effect to the conflicts of laws principles thereof other than Sections 5-1401 and 5-1402 of the General Obligations Law of such State.

(b) Each of Eclat and Secured Party (together, the "**Parties**" and individually, a "**Party**") irrevocably submits to the jurisdiction of the state and federal courts sitting in The City of New York, borough of Manhattan, for the adjudication of any dispute hereunder or in connection herewith, and hereby waives, and agrees not to assert in any suit, action or other proceeding, any claim that it is not personally subject to the jurisdiction of any such court or that such court, action or other proceeding is improper or is an inconvenient venue for such proceeding. Final non-appealable judgment against any Party in any such action, suit or other proceeding shall be conclusive and may be enforced in any jurisdiction by suit on the judgment. Nothing contained in this Agreement shall affect the right of any Party to commence legal proceedings in any court having jurisdiction, or concurrently in more than one jurisdiction, or to serve process, pleadings and other legal papers upon another Party in any manner authorized by the laws of any such jurisdiction. Each Party irrevocably waives, to the fullest extent permitted by applicable law, any objection which it may have to the laying of venue of any action, suit or other proceeding arising out of this Agreement, brought in the courts of the State of New York or in the United States District Court for the Southern District of New York, and any claim that any such action, suit or other proceeding brought in any such court has been brought in an inconvenient forum.

(c) Each Party waives any right to demand a trial by jury in any action, suit or other proceeding arising out of this Agreement.

(d) To the extent that the Parties may, in any suit, action or other proceeding brought in any court arising out of or in connection with this Agreement, be entitled to the benefit of any provision of law requiring any Party in such suit, action or other proceeding to post security for the costs of any other Party, or to post a bond or to take similar action, the Parties hereby waive such benefit, in each case to the fullest extent now or hereafter permitted under any applicable laws.

9. **Additional Definitions.** All references to the plural herein shall also mean the singular and to the singular shall also mean the plural unless the context otherwise requires. All references to Eclat and Secured Party shall include their respective successors and assigns. The words "hereof", "herein", "hereunder", "this Agreement" and words of similar import when used in this Agreement shall refer to this Agreement as a whole and not any particular provision of this Agreement and as this Agreement now exists or may hereafter be amended, modified, supplemented, extended, renewed, restated or replaced. The word "including" when used in this Agreement shall mean "including, without limitation". The words "it" or "its" as used herein shall be deemed to refer to individuals and to business entities.

"**Copyright**" means (i) all copyrights and moral rights, including the legal right provided by the Copyright Act of 1976, as amended, to the expression contained in any work of authorship fixed in any tangible medium of expression together with any similar rights arising in any other country as a result of statute or treaty, and all registrations, applications, renewals, extensions and reversions thereof.

"**Event of Default**" means (i) the incurrence and continuance of an Event of Default (as defined in the Facility Agreement and (ii) the failure by Eclat to comply with the Royalty Agreement.

"**Intellectual Property**" means any intellectual property, in any medium, of any kind or nature whatsoever, now or hereafter owned or acquired or received by Eclat or in which Eclat now holds or hereafter acquires or receives any right, interest or license, and shall include, in any event, any copyright rights, copyright applications, copyright registrations and like protections in each work of authorship and derivative work, whether published or unpublished, any patents, patent applications and like protections, including improvements, divisions, continuations, renewals, reissues, extensions, and continuations-in-part of the same, trademarks, service marks and any applications therefor, whether registered or not, and the goodwill of the business of Eclat connected with and symbolized thereby, know-how, operating manuals, inventions, formulae, processes, gene sequences, cell lines, assays, biological materials, compounds, compound libraries, research, clinical and commercial compounds, along with the associated active pharmaceutical ingredients and related formulations (other than Inventory), new drug applications and investigational new drug applications or other regulatory filings relating to any drugs or compounds, trade secret rights, rights to unpatented inventions, and any claims for damage by way of any past, present, or future infringement of any of the foregoing, and any licenses to use any of the foregoing.

"**Mark**" means any word, name, symbol, logos or device used by a Person to identify its goods or services, whether or not registered, all goodwill associated therewith, and any right that may exist to obtain a registration with respect thereto from any governmental body and any rights arising under any such application, together with all registrations, renewals, extensions and reversions thereof. As used in this Agreement, the term "Mark" includes all of the foregoing, including trademarks and service marks.

"**Obligations**" means:

(1) the full and prompt payment by Eclat when due of all obligations and liabilities to Secured Party under the Royalty Agreement;

(2) the full and prompt payment by Flamel US Holdings, Inc. when due of all obligations and liabilities to Secured Party under the Facility Agreement;

(3) any and all sums advanced by Secured Party to preserve the Collateral or to preserve the Security Interest; and

(4) in the event of any proceeding for the collection or enforcement of any obligations or liabilities of Eclat referred to in the immediately preceding clauses (1), (2) and (3), the reasonable and documented out-of-pocket expenses of re-taking, holding, preparing for sale, selling or otherwise disposing of or realizing on the Collateral, or of any other exercise by Secured Party of its rights hereunder, together with reasonable and documented out-of-pocket attorneys' fees and court costs.

"**Patent**" means any patent granted by the United States Patent and Trademark Office or by the comparable agency of any other country, and any renewal, thereof, and any rights arising under any patent application filed with the United States Patent and Trademark Office or the comparable agency of any other country and any rights that may exist to file any such application, including all continuations, divisional, continuations-in-part and provisionals and patents issuing thereon, and all reissues, reexaminations, substitutions, renewals and extensions thereof.

"**Person**" or "**person**" shall mean any individual, sole proprietorship, partnership, corporation, limited liability company, limited liability partnership, business trust, unincorporated association, joint stock corporation, trust, joint venture or other entity or any government or any agency or instrumentality or political subdivision thereof.

"**Product Intellectual Property**" shall mean all Proprietary Rights held or licensed by Eclat and their Affiliates that is, or may hereafter be, necessary to develop, make, have made, promote, market or sell the Products in the United States.

"**Product Regulatory Rights**" shall mean each and every investigational new drug application or new drug application and/or state license or registration that is held or obtained (if any) that is necessary to develop, conduct clinical trials relating to, manufacture, have manufactured, distribute, promote, market or sell the Products in the United States.

"**Products**" shall mean (i) the drugs [***], [***], [***] and [***], and (ii) [***].

"**Proprietary Rights**" means, with respect to a Person, all Copyrights, Marks, Trade Names, Trade Secrets, Patents, and Intellectual Property owned or used by such Person.

"**Trade Names**" means any words, name or symbol used by a Person to identify its business.

"**Trade Secrets**" means business or technical information of any Person including, but not limited to, customer lists, marketing data and know-how, that is not generally known to other Persons who are not subject to an obligation of nondisclosure and that derives actual or potential commercial value from not being generally known to other Persons.

"**UCC**" shall mean the Uniform Commercial Code as in effect in the State of New York and any successor statute, as in effect from time to time (except that terms used herein which are defined in the Uniform Commercial Code as in effect in the State of New York on the date hereof shall continue to have the same meaning notwithstanding any replacement or amendment of such statute); provided, however, that if, by reason of mandatory provisions of law, any or all of the attachment, perfection or priority of the Security Interest in any Collateral is governed by the Uniform Commercial Code as in effect in a jurisdiction other than the State of New York, the term "UCC" shall mean the Uniform Commercial Code as in effect at such time in such other jurisdiction for purposes of the provisions hereof relating to such attachment, perfection or priority and for purposes of definitions related to such provisions.

10. Notices**.** Any notice, request or other communication to be given under this Agreement shall be in writing. Such communication shall be deemed to have been duly given or made when it shall be delivered by hand, courier (confirmed by facsimile), or facsimile or electronic mail (with a hard copy delivered within two (2) Business Days) to the Party to which it is required or permitted to be given at such Party's address specified below or at such other address as such Party shall have designated by notice to the other Parties.

For Eclat:

Eclat Pharmaceuticals LLC
699 Trade Center Blvd., Suite A
Chesterfield, MO 63005
Attention: [ ]

with a courtesy copy to:

Flamel Technologies S.A.
33, avenue du Dr. Georges Levy –
Parc Club du Moulin à Vent
69693 Vénissieux Cedex – France
Attention: [ ]

For the Secured Party:

c/o Deerfield Management Company, L.P.
780 Third Avenue, 37th Floor
New York, NY 10017
Attention: Structured Products

with a courtesy copy to:

Katten Muchin Rosenman LLP
575 Madison Avenue
New York, New York 10022-2585
Attention: Mark I. Fisher
Facsimile: (212) 894-5877

11. General.

(a) This Agreement shall be binding upon the assigns or successors of Eclat and shall inure to the benefit of and be enforceable by Secured Party and its successors and assigns.

(b) This Agreement contains the entire understanding of the Parties with respect to the matters covered hereby and supersedes any and all other written and oral communications, negotiations, commitments and writings with respect hereto. The provisions of this Agreement may be waived, modified, supplemented or amended only by an instrument in writing signed by each Party.

(c) If any provision contained in this Agreement shall be invalid, illegal or unenforceable in any respect under any law, the validity, legality and enforceability of the remaining provisions shall not be affected or impaired thereby. The Parties shall endeavor in good faith negotiations to replace the invalid, illegal or unenforceable provisions with valid provisions the economic effect of which comes as close as possible to that of the invalid, illegal or unenforceable provision.

(d) This Agreement and any document, certificate or statement delivered pursuant thereto or in connection herewith shall be considered to have been relied upon by the Parties and shall survive the execution and delivery of this Agreement regardless of any investigation made by any Party, and shall continue in force until the Obligations shall have been fully paid and performed, and Secured Party shall not be deemed to have waived, any default that may arise by reason of any representation or warranty proving to have been false or misleading, notwithstanding that the Secured Party may have had notice or knowledge that such representation or warranty was false or misleading on the date hereof.

(e) Neither the failure of, nor any delay on the part of, any Party in exercising any right, power or privilege hereunder, or under any agreement, document or instrument mentioned herein, shall operate as a waiver thereof, nor shall any single or partial exercise of any right, power or privilege hereunder, or under any agreement, document or instrument mentioned herein, preclude other or further exercise thereof or the exercise of any other right, power or privilege; nor shall any waiver of any right, power, privilege or default hereunder, or under any agreement, document or instrument mentioned herein, constitute a waiver of any other right, power, privilege or default or constitute a waiver of any default of the same or of any other term or provision. No course of dealing and no delay in exercising, or omission to exercise, any right, power or remedy accruing to the Secured Party upon any default under this Agreement, or any other agreement shall impair any such right, power or remedy or be construed to be a waiver thereof or an acquiescence therein; nor shall the action of the Secured Party in respect of any such default, or any acquiescence by it therein, affect or impair any right, power or remedy of the Secured Party in respect of any other default. All rights and remedies herein provided are cumulative and not exclusive of any rights or remedies otherwise provided by law.

12. Release of Collateral.

The Secured Party shall promptly upon the request of Eclat (a) release any lien on any Collateral granted to the Secured Party under this Agreement upon the payment and performance in full of all Obligations, and at Eclat's expense, promptly (x) deliver to Eclat any Collateral in the Secured Party's possession following the release of such Collateral and (y) execute and deliver to Eclat such documents as Eclat may reasonably request to evidence such release.

[Signature Page Follows]

IN WITNESS WHEREOF, each of the Parties hereto has caused this Agreement to be executed and delivered by its duly authorized officer on the date first set forth above.

ECLAT PHARMACEUTICALS LLC

By: /s/ Michael S. Anderson
Name: Michael S. Anderson
Title: CEO

DEERFIELD PRIVATE DESIGN FUND II, L.P.
By: Deerfield Mgmt L.P., its General Partner
By: J.E. Flynn Capital, LLC, its General Partner

By: /s/ James E. Flynn
Name: James E. Flynn
Title: President

DEERFIELD PRIVATE DESIGN INTERNATIONAL II, L.P.
By: Deerfield Mgmt L.P., its General Partner
By: J.E. Flynn Capital, LLC, its General Partner

By: /s/ James E. Flynn
Name: James E. Flynn
Title: President

SCHEDULE 4(c)
TO
SECURITY AGREEMENT

CHIEF EXECUTIVE AND MAILING OFFICE
LOCATION OF COLLATERAL

Subsidiaries of Flamel Technologies S.A.

Flamel Technologies, Inc.

Flamel US Holdings Inc.

Éclat Pharmaceuticals, LLC

Talec LLC

Exhibit 12.1

CERTIFICATION PURSUANT TO
SEC RULE 13a-14(a)/15d-14(a)
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael S. Anderson, certify that:

1. I have reviewed this annual report on Form 20-F of Flamel Technologies S.A. (the "**Company**");
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this report;
4. The Company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Company and have:
   a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.
   c. evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   d. disclosed in this report any change in the Company's internal control over financial reporting that occurred during the period covered by this report that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and
5. The Company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the Audit Committee of the Company's Board of Directors (or persons performing the equivalent functions):
   a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and
   b. any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

Date: April 30, 2013
/s/ Michael S. Anderson
Michael S. Anderson
Chief Executive Officer

Exhibit 12.2

CERTIFICATION PURSUANT TO
SEC RULE 13a-14(a)/15d-14(a)
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Siân Crouzet, certify that:

1. I have reviewed this annual report on Form 20-F of Flamel Technologies S.A. (the "**Company**");
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this report;
4. The Company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Company and have:
   a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.
   c. evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   d. disclosed in this report any change in the Company's internal control over financial reporting that occurred during the period covered by this report that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and
5. The Company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the Audit Committee of the Company's Board of Directors (or persons performing the equivalent functions):
   a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and
   b. any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

Date: April 30, 2013
/s/ Siân Crouzet

Siân Crouzet
Principal Financial Officer

Exhibit 13.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Flamel Technologies S.A. (the "**Company**") on Form 20-F for the fiscal year ended December 31, 2012, filed with the Securities and Exchange Commission on the date hereof (the "**Report**"), I, Michael S. Anderson, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Michael S. Anderson

Michael S. Anderson
Chief Executive Officer
April 30, 2013

Exhibit 13.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Flamel Technologies S.A. (the "**Company**") on Form 20-F for the fiscal year ended December 31, 2012, filed with the Securities and Exchange Commission on the date hereof (the "**Report**"), I, Siân Crouzet, Principal Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Siân Crouzet

Siân Crouzet
Principal Financial Officer
April 30, 2013

Exhibit 23.1

CONSENT OF
INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 of Flamel Technologies S.A., Nos. 333-137844, 333-134638, 333-111725, 333-109693, 333-12542 and 333-177591 and on Form F-3 No. 333-183961 of our report dated April 30, 2013, relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 20-F.

Lyon, France, April 30, 2013

PricewaterhouseCoopers Audit

Represented by
/s/ Bernard Rascle
Bernard Rascle (signed)